BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025159
Article Type:	Research
Date Submitted by the Author:	04-Jul-2018
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Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

TITLE PAGE

Short-term impact of introducing a soft opt-out organ donation system in Wales: Before and after study.

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Abstract

Objectives
To determine the impact on consent and explore family and professional experiences.
Design. Before and after (18 months) observational study and process evaluation.
Setting: NHS Blood and Transplant and NHS hospitals in Wales.
Participants. 205 potential organ donor cases in Wales; 6 cases who died in England: total 211 cases. 88 relatives of 60/211 cases; 19 professionals.
Interventions: The Act and implementation strategy.
Primary and secondary outcomes: Consent rates and numbers of potential organ donors compared with previous years; views and experiences of family members and professionals.
Results: The overall consent rate was 60.9% (125/205), showing a recovery from 48.5% in 2014/15 but not significantly different from the three preceding years. 22.4% (46/205) were deemed consented donors: consent rate 60.8% (28/46). Deceased donors did not increase:101 compared with 104, 21 months pre and post implementation. The media campaign worked but was not memorable and had gaps. Families did not fully understand deemed consent, but the decision-making framework was welcomed. Organ donor registration increased from 34% to 38%. 79% (162/205) had registered or expressed a decision. The media campaign did not explain the changed family role. Family members overrode 31/205 (15%) decisions to donate. It was not possible to determine if overriding a decision was what the family wanted or patient wanted. Health systems issues negatively affected consent rates and donor numbers.
Conclusion: Consent rates increased but not significantly. The long-term impact on donor numbers is unclear. Concerns about a potential backlash and mass opting out were not realised. Family members need pre and not post implementation intervention to better explain their role. Policymakers should not assume that soft opt-out systems by themselves simply need more time to have a meaningful effect. Further longitudinal studies are required to monitor if positive trends in consent rates translate to increased donor numbers.

Strengths and weaknesses of the study

- This is the first depth study to evaluate implementation of a soft-opt out system.
- Data were collected for 18 months on all cases and findings were contextualised with retrospective data, and data from a large and robust process evaluation.
- In contrast to previous studies, recruitment of a large purposive sample of family members who had a diverse range of views on organ donation was successful and target numbers were surpassed.
- A large group of patient and public representatives worked with researchers to co-produce the study, which has resulted in a more grounded interpretation of findings.
- Due to finite time and resources, NHS staff working in Welsh hospitals were not interviewed to ascertain their perspectives.

Original Protocol

Noyes J, Morgan K, Walton P, Roberts A, Mclaughlin L, Stephens M. Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: mixed-method study protocol. **BMJ Open.** 2017 Oct 12;7(10):e017287. doi: 10.1136/bmjopen-2017-017287

Funding statement

The study was funded by Health and Care Research Wales. Project Reference 1129.

Competing interests statement

There are no known competing interests.

Patient consent

Article contains no identifiable personal medical information.

Data sharing statement

Additional unpublished data are not publicly available.

INTRODUCTION

Around 6500 people are waiting for organ transplants in the United Kingdom (UK).[1] Organ transplantation is cost-effective and improves quality of life for recipients.[2] Organ donation consent rates in the UK need to improve to keep up with demand for transplants.[3] Under the opt-in system in Wales, consent rates for deceased organ donation ranged between a high of 53.6% to a low of 48.5% between 2013-2015.[4] In contrast consent rates in some other European countries are much higher. For example, in Spain consent ranges from 80-85% in an opt-out system in which all citizens are automatically assumed to consent to organ donation unless they choose to state otherwise. [5]

The British Medical Association, patient groups and newspapers[6-7] have lobbied for the introduction of an opt-out system to replace the current opt-in system in the respective UK nations (England, Scotland, Wales, Northern Ireland). The UK nations have separate, and in the case of Scotland, Wales and Northern Ireland devolved, responsibilities for health. There are two types of 'opt-out' system: a 'hard' opt-out where the family are not consulted or a 'soft' opt-out where the family are consulted. Opinion is starkly divided as to the benefits of introducing either form of opt-out system of organ donation compared with reorganisation of the current opt-in system to increase consent rates.[8-9]

Following an extensive public consultation, the Human Transplantation (Wales) Act 2013 introduced a soft opt-out system of organ donation, which was fully enacted on 1st December 2015.[10] The purpose of the Act is to make it easier for people to donate their organs to benefit patients. The primary aim is to increase consent rates. In the Welsh soft opt-out system presumed consent means that unless the deceased person has expressed a decision in life (either for or against being be an organ donor) then consent will be assumed (or deemed in Wales). Family members are expected to support the donation decision made by their relative in life.

How the intervention is intended to work

A detailed description of the components and how the intervention is intended to work can be found in the study protocol.[4] In summary, the Act, media campaign and implementation strategy were conceptualised as a complex behaviour change intervention. The Act changed the principles of consent to deceased organ donation from an opt-in to a soft opt-out system for adults 18 years or over; voluntarily resident for 12 months or more in Wales; who have not made an expressed decision regarding organ donation; and is competent to understand the notion of deemed consent. The individual must also die in Wales for the Act to apply. In addition to the public media campaign, there was an accompanying implementation strategy for National Health Service (NHS) and NHS Blood and Transplant (NHSBT) staff, which required amending clinical protocols and procedures and retraining large numbers of staff and all Specialist Nurses in Organ Donation (SNODs) covering Wales. The success of the Act depended on behaviour change of the public and professionals. The theory is that the neutral media campaigns supporting implementation will facilitate the behaviours in Welsh citizens outlined in Box 1.

Box 1. Intended behaviours of the citizens of Wales under the soft opt-out system.[4]

- opt-in or opt-out on the organ donor register (registered decision), with the option of appointing a patient representative
- discuss opt-in or opt-out donation decision with families and friends (express decision)
- do nothing and it will be assumed that the person does not object to organ donation (deemed consent)
- families will put aside their own views on donation and respect the decision of the deceased person made in life.

There are few examples where soft opt-out systems have been implemented in the context of rigorous research and no examples of process evaluations with family members who were approached about organ donation when a change to a soft opt-out system has been implemented. The main aim of the study was to determine the impact on consent for deceased organ donation, and to explore processes, and family and professional experiences of the new soft opt-out system in Wales.

METHODS

We used NHSBT routinely collected data (including the Potential Donor Audit) on all potential organ donor cases, and organ donor registration activity for 18 months after the 1st December 2015 when the soft opt-out was implemented in Wales, compared with up to three years pre-implementation. For the purposes of his study a potential organ donor was defined as a patient who is eligible for organ donation and whose family is approached for a formal organ donation discussion. SNODs completed an additional research data collection form for each case they attended after 1st December 2015. Welsh Government shared comparative figures on numbers of deceased donors for 21 months before and after implementation.[11] Family members and professionals participated in interviews or focus groups, with the option for family members to complete an additional questionnaire on their views and experiences of organ donation under the soft opt-out system. Researchers also compiled detailed fieldnotes. The study design and recruitment is shown in Figure 1, and described in more detail in the published protocol.[4] The multiple sources of data are summarised in supplemental file 1.

Primary and secondary outcomes: Consent rates and numbers of organ donors compared with previous years; views and experiences of family members and professionals.

Participants. All 205 potential organ donor cases in Wales were included, of which 182/205 cases met the criteria for a known decision or having their consent deemed. In addition, 6/38 potential Welsh organ donor cases who died in English hospitals were purposively sampled and followed up (making 211 cases in total). The relatives of all 211 cases were invited to complete a questionnaire and or participate in a depth interview. Recruitment was monitored to ensure that the sample represented all organ donation modes of consent and outcomes. Eighty-eight relatives of 60/211 cases, and 19 SNODs and managers provided depth data on their views and experiences of the soft opt-out system.

Data collection and analysis

NHSBT routinely collected data on each case

NHSBT statisticians compiled summary reports of descriptive statistics for the 18 month post-implementation period and provided reports of comparative retrospective data and statistical significance. It was not always possible to conduct a consistent before and after comparison as the Act introduced new consent pathways and options that were not previously available (such as opting out on the organ donor register and deemed consent). Data were grouped by mode of consent (expressed and registered opt-in and opt-out; deemed, and family consent), and total numbers of families approached.

After implementation categorical questionnaire data

SNOD and family completed questionnaires containing structured categorical options (such as Yes, No, Uncertain) were organised by the different mode of consent options and outcomes, collated in SPSS version 22[12] and analysed using descriptive statistics.

After implementation narrative textual data

With consent, interviews were digitally recorded and transcribed verbatim. Free text was extracted from questionnaires. Transcripts and free text were analysed using NVivo.[13] The Framework approach to coding narrative data was used for analysis.[14]

Ethics

The protocol was approved on 23/10/15 by NHSBT Research, Innovation and Technology Advisory Group (RINTAG). This approval included agreement to share anonymised NHSBT data. The study was approved by the Wales Research Ethics Committee 5 NHS research ethics committee (IRAS number 190066; Rec Reference 15/WA/0414 on 25/11/2015) and the NHSBT Research and Development Committee (NHSBT ID: AP-15-02 on 24/11/2015). Bangor University was the study sponsor.

Patient and Public Involvement

This was a co-productive study with extensive patient and public involvement of over 50 people and organisations in the design, analysis and interpretation of data. A 2-day residential meeting and an end of study event were convened to discuss and interpret findings.

RESULTS

There were 205 deceased donors in Wales of which 88.7% (182/205) met the criteria for a known decision or having their consent deemed (Figure 1 and Table 1). The remaining 11.2% (23/205) cases met the criteria for the 'family' mode of consent as the deceased person was a child or lacked mental capacity. The consent rate for all modes of consent was 60.9% (125/205), showing a recovery from the dip to 48.5% in 2015/15 but not significantly different from the three preceding years. The consent rate for 182/205 cases that met the criteria for a known decision or deemed consent was 64.2%. Just over 22% (46/182) of cases were deemed consented donors with a consent rate 60.8% (28/46).

Seventy-nine percent (162/205) had registered or expressed a decision, of which 62.4% (128/205) of cases had registered or expressed their decision to opt-in. Fifty-seven percent (73/128) registered to opt-in on the organ donor register, and 22.6% (29/128) verbally expressed to opt-in with their families during their lifetime. Just over 16.5% (34/205) opted-out: 8/34 opted-out on the organ donor register and 26/34 expressed to their families that they wanted to opt-out.

Of the 125/205 cases where consent to deceased donation was supported by family members, 69.6% (87/125) proceeded to donation. The number of deceased donors remained relatively static (101 compared with 104 21 months pre and post implementation).[11] The number of potential donors however fell over this period, so although the overall donor numbers stayed roughly the same, this was in the context of fewer potential donors. Organ donation registration increased from 34-38%. As of June 2017, 1,181,709 people in Wales had opted-in and 176,011 opted-out, which is 6% of the population and less than the Government anticipated would opt-out.

Families approached by subsequent mode of consent: Deceased organ donation Wales	**Retrospective before**			**Prospective after implementation of the soft opt-out on 1st December 2015**			
	April 2012 – March 2013 12 months	**April 2013 – March 2014 12 months**	**April 2014-March 2015 12 months**	**Dec 2015- Mar 2015 4 months**	**April 2016 – March 2017 12 months**	**April 2017 May 2017 2 months**	**Total Dec 2015- May 2017 18 months**
Total families approached: number of cases	161	169	153	54	141	10	205
Total cases that met the criteria for a known decision or having their consent deemed. Excludes family consent (child, not Welsh resident, lacks mental capacity)	N/A	N/A	N/A	51	124	7	182
Expressed consent:	56 Registered opt in on ODR 48 Verbally expressed opt in 7 Other 1	62 Registered opt in on ODR 52 Verbally expressed opt in 10	48 Registered opt in on ODR 43 Verbally expressed opt in 5	21	76	5	102/205 (49.7%) Registered opt in on ODR 73 Verbally expressed opt in 29
Deemed consent	N/A	N/A	N/A	13	31	2	46/205 (22.4%)
Family consent	105	107	105	3	17	3	23/205 (11.2%)
Total patient opt-outs:	N/A	N/A	N/A	17	17	0	34/205 (16.5%)
Registered opt out on ODR	N/A	N/A	N/A	3	5	0	8
Verbally expressed opt out	N/A	N/A	N/A	14	12	0	26
Mode of consent ascertained (consent rate)							
Total consent ascertained*	81/161 (50.3%)	91/169 (53.8%)	70/153 (45.8%)	29/54 (53.7%)	90/141(63.8%)	6/10 (60.0%)	125/205 (60.9%)
Total consent for cases that met the criteria for a known decision or having their consent deemed.	N/A	N/A	N/A	27/51 (52.9%)	85/124 (68.5%)	5/7 (71.4%)	117/182 (64.2%)
Expressed consent	48/56 (85.7%)	53/62 (85.5%)	37/48 (77.1%)	18/21 (85.7%)	66/76 (86.8%)	5/5 (100%)	89/102 (87.2%)
Deemed consent	N/A	N/A	N/A	9/13 (69.2%)	19/31 (61.2%))	0	28/46 (60.8%)
Family consent	33/105 (31.4%)	38/107 (35.5%)	33/105 (31.4%)	2/3 (66.6%)	5/ 17 (29.4%)	1/3 (33.3%)	8/23 (34.7%)
Overrides by family members							
Total overrides by family members	8/161 (5%)	9/169 (5.3%)	11/153 (7.2%)	7/54 (12.9%)	22/141 (29.1%)	2/10 (20%)	31/205 (15.1%)
ODR overrides	8/48 (16.7%)	7/52 (13.5%)	10/43 (23.3%)				12/73 (16.4%)
Other expressed overrides	0	2/10	1/5				1/29 (3.4%)
Deemed consent	N/A	N/A	N/A				18/46 (39.1%)
Proceeding donors by mode of consent							
Expressed consent	26/48	33/53	28/37	13	43	4	60/89 (67.4%)

Deemed consent	N/A	N/A	N/A	9	11	0	20/28 (71.4%)
Family consent	24/33 (72.3%)	21/38 (55.3%)	26/33 (78.8%)	2	4	1	7/8 (87.5%)
Total	52/81 (64.2%)	54/91 (59.3%)	60/70 (85.7%)	24	58	5	87/125 (69.6%)
Organs donated by mode of consent							
Expressed consent: Verbal or ODR registration	89	108	100	44	136	17	197
Deemed consent	N/A	N/A	N/A	31	39	0	70
Family consent	88	69	78	12	10	4	26
Total	177	177	178	87	185	21	293
Organs transplanted by mode of consent							
Expressed consent: Verbal or ODR registration	83	97	87	36	116	15	167
Deemed consent	N/A	N/A	N/A	26	33	0	59
Family consent	82	63	62	12	9	2	23
Total	165	160	149	74	158	17	249
Comparative total consent ascertained rate for England	57.9%	59.6%	58.5%		62.5%		60.9%
Comparative donor numbers* Figures shared by Welsh Government for 21 months pre and post[8] *Before and after change not statistically significant	21 months pre - 101			21 months post- 104			

Table 1. Before and after results.

Process evaluation

We report summarised results from the process evaluation that help explain why consent rates have improved but are not yet significantly better than before. Elsewhere we report more detailed process findings of the nurse-led implementation of the soft opt-out system and implications for nursing practice.[15]

Deemed consent

Deemed consent is a new mode of consent in the organ donation system. Although families did not fully understand deemed consent, many welcomed the decision-making framework and the help given by SNODs to explain what deemed consent meant and how it was applied. Only 18% (15/85) of family member(s) that we spoke to fully accepted that 'doing nothing' was a choice. Deemed consent was generally considered as a 'non-decision' by family members who would have preferred their relatives to have registered their decision on the organ donor register or talked about their donation decision with them during their lifetime (express decision). See Box 2 for examples of quotes from family members and professionals.

Expressed decisions

The verbally expressed opt-out decisions were the most difficult for SNODs to unpick as there was frequently disagreement within families as to whether their relative wanted to be an organ donor or not. The principles of obtaining the 'last known decision of the deceased' as directed in the Human Tissue Act 2004[16] takes primacy of the 2013 Act in Wales[10], and SNODs are therefore required to ascertain the last known decision of the deceased person. SNODs generally found it difficult to disentangle the personal negative views on organ donation shared by individual family members and the actual expressed decision of the potential deceased donor during their lifetime. Some individual family members who appeared to be against organ donation informed the SNOD that their relative had told them in the weeks before death that their relative no longer wanted to be an organ donor. This last known expressed opt-out decision frequently appeared to be contrary to what all the other family members were saying about their relative wanting to be an organ donor. Despite saying that their relative had wanted to donate their organs, families generally did not feel able to go ahead if an individual family member disagreed. These cases were classified as expressed opt-outs even through the majority of family members felt that their relative had expressed that they wanted to donate their organs (opt-in). None of the 81 cases who registered their decision on the organ donor register had appointed a representative to convey the donation decision on their behalf, which could have helped clarify the potential donor's decision in situations where family members disagreed.

Family overrides of their relative's donation decisions made in life

Not including the expressed decisions that appeared to be overridden by family members using the last known decision, family members overrode 15.1% (31/205) opt-in decisions to donate, including 16.4% (12/73) organ donor registered opt-in decisions; 3.4% (1/29) verbally expressed opt-in decisions, and 39.1% (18/46) deemed consents. Box 3 outlines the reasons.

Although numbers are too small to undertake any meaningful statistical analysis, and the introduction of new modes of consent (with new potential opportunity to override) make direct comparisons difficult to interpret, there was an observed upward trend in family overrides following introduction of the soft-opt out system (Table 1). For the three years prior to implementation family overrides ranged from 5-7.2%. Post implementation it was 15.1% over 18 months, and 29.1% in 2016/17. Some of the increase can be explained by the introduction of deemed consent, which provided a new opportunity to override that did not exist before.

Box 3. Reasons why family member(s) of 31 cases felt unable to support the organ donation decision:

Health systems issues

- Time frame to organ donation was considered too long (8).
- No Specialist Nurse in Organ Donation available (3).
- The perceived (poor) quality of NHS care (3).
- The perceived (poor) quality of NHSBT care (1).

Family issues

- Family dynamics, disagreements (4).
- Unable to put their own negative views on organ donation aside (10).
- Unable to accept the donation decision (organ donor register) (2).
- Unable to accept deemed consent was a choice that supported organ donation (3).

* Out of 31 cases, more than one reason might apply

Non-proceeding consented donors

Of the 125/205 consenting donors, 69.6% (87/125) proceeded to donation. The reasons for non-proceeding consented donors were not associated with the system of consent and included: new medical information that prevented donation; unavailability of theatre time or transplant team with a timeframe that was considered reasonable by families; prolonged time to asystole, organs not a match to recipients or not accepted by centres when offered.

Implementation issues

There were seven implementation issues:

Media campaign

The media campaign worked but was not memorable and had gaps. In response to the campaign organ donor registration increased (from 34% - 38%) and people talked about their organ donation decisions with their families. The media campaign did not however explain the changed family role of supporting their relative's donation decision made in life. Many family members still thought that it was their decision to make.

Establishing the correct mode of consent

The Act resulted in additional modes of consent and SNODS sometimes found it challenging to determine which mode of consent applied in each case. The mode of consent could change as the SNOD spent time talking with family members to establish the facts. They generally first checked the organ donor register, then established if a decision had been verbally expressed, and established the last known decision. They determined if the deceased person met the eligibility criteria for deemed consent and only if the deceased person had not registered or expressed a decision, did deemed consent apply. This process was challenging and SNODs found it difficult to disentangle the donation decision of the deceased person from that of the views on organ donation of family members.

SNODs tendency to mirror family language (predominantly based on the previous system)

SNODS found it challenging to adopt the required changes to the language that they used with family members from establishing the ‘wishes’ of the deceased person in the opt-in system to establishing their ‘donation decision’ in the soft opt-out system. SNODs continued to mirror the language used by families, which generally focussed on ‘wishes’ and not ‘decisions’.

Obtaining the required standard of evidence from families to override a deceased person’s organ donation decision

The Act required a standard of evidence from family member(s) to override an organ donation decision of the deceased person (written or witnessed conversation). This was found to be unrealistic to implement in practice and SNODs accepted a lesser standard (a family member’s uncorroborated say so).

Health systems issues

As described above, health systems issues also affected and prevented family member support for an opt-in donation decision. In addition, family members said that it was not always possible for them to stay at or near the hospital at no charge whilst donation proceeded and so they were not able to support their relative’s decision to donate.

Welsh residents who died in English hospitals

It is relatively common for Welsh residents to receive intensive care in English hospitals (especially in North Wales and along the border). Thirty-eight Welsh residents who died in England were counted in the English NHSBT audits and the opt-in system in England applied. The families of 6/38 cases (purposively sampled) whom we followed up were confused when Welsh patients died in English hospitals as to which system applied. Consent was given in 5/6 (83.3%) cases.

Family members who lived in England

Family members who were approached about organ donation frequently lived in England and had not been exposed to the media campaign released in Wales. They were generally not aware of the differences between the opt-in system in England and the opt-out system which applied to their relative in Wales.

Box 2. Illustrative quotes	
Role of Specialist Nurses in Organ Donation	*"Those nurses are some of the loveliest people you will ever meet. What they do is extraordinary. The care and compassion that they showed us at such a difficult time we will never forget it." (ID02 Female, child of deceased)* *"They made us feel like something amazing was about to happen. They explained everything perfectly, helped us through everything." (ID64 Male, spouse of deceased)* *"We didn't get to speak to the specialist nurses until it was all over. If we had I think it would have made such a difference to our negative experience." (ID08 Male, parent of deceased)* *"The way they came across was so lovely, not sympathetic or patronising, it is hard to explain, it was like they just understood." (ID20, Male spouse of deceased)*
SNOD views on trying to establish the correct donation pathway in a presumptive soft opt-out system.	*"We are supposed to be having a presumptive conversation and at the same time establishing if the deceased person had ever talked about organ donation. I don't know if you can do both really, and it has tripped us up a bit, it doesn't really make sense when you think about it".(SNOD, focus group)*
Awareness of the new Law	*"...When they mentioned organ donation, I immediately thought this must be because of this new law. It helped us because none of us knew at the time what Mammy wanted." (ID06 Female, daughter of deceased)*
Doing nothing – deemed consent	*"Doing nothing causes problems for families. We should express a decision because if you do nothing and you don't speak about it, then how is your family going know what you want to do, they would always worry if you really wanted (or didn't) want it." (ID10 Female, daughter of deceased)*
Family member(s)	*"Well we were all just so surprised when she*

overriding their relative's donation decision	*said that she had talked about it with mam last week and that she expressed that she didn't want to be a donor. It was at odds with what I knew and what I had always presumed - that she wanted to be an organ donor".* *"Now thinking about it perhaps if somebody had said that there was somebody downstairs waiting for a kidney or whatever we might have thought more about the implications of not supporting the decision. But it was really hard seeing my daughter so upset at the thoughts of the organ donation going ahead. In the end we went with what my daughter wanted." (ID57 Male, spouse of deceased)*
Health systems issues that prevented organ donation	*"At the start we thought yes of course, but it all went on too long. In the end we all thought this isn't dignified. We don't regret saying no, we held on as long as we could." (ID13 Female, daughter of deceased)*
SNOD challenges concerning implementation and language of the new Act – changing from 'wishes' to 'decisions'	*"It is hard because it is a language that we have always used intuitively and now we are using a language that has been written for us. I mean we do loads of work around language now, but it doesn't always align itself with our language. We are used to using words like 'gift' which sits along nicely with 'a wish' and it makes sense to me, but deemed consent is a very technical language, and I think we are trying to soften it when we talk to families. This is really complicated because for me they are such different languages". (SNOD, focus group)*

DISCUSSION

Consent rates in Wales have improved but the differences are not yet statistically significant. It is too early to tell if the soft-opt out system will be successful in further increasing consent rates. Although there was general support for the soft opt-out system, decisions made by the citizens of Wales during life were not consistently supported as intended by family members in death. Family members have yet to accept ‘doing nothing’ (deemed consent) as a positive decision in support of organ donation. The fact that the consent rate obtained via deemed consent is the same as the overall consent rate is an important and reassuring finding that contradicts Shaw’s assumption that families are more likely to overrule a consent that is merely presumed.[17] Family members would however prefer their relatives to register or express their donation decision during their lifetime. Overall family overrides were generally higher than in the years preceding implementation and it was commonly not possible to determine if overriding a decision was what the family wanted or what the patient wanted.[17] At an individual potential donor level it has been made easier to convey a decision to donate organs. Sixty percent of cases were either registered on the organ donor register or had discussed their donation decision with family member(s), and as of March 2018, 39% of the population are now (March 2018) registered to donate on the organ donor register. Any fears that introducing an opt-out would cause a backlash by somehow changing the concept of the ‘gift’ of organ donation has not been realised. Only a relatively small number of people opted out (6%), and people are still opting in more than previously. Consent rates were also negatively affected by multiple health system issues that impacted on family member’s willingness to support their relative’s opt-in decision to donate, and the ability of consented donors to proceed to donation. Of note, patient and public representatives supported interviewees experiences that the hospital-based accommodation, facilities and support offered to potential donor families were inadequate. All these systemic issues are potentially fixable by NHS managers.

Data were collected for 18 months on all cases and findings were contextualised with a large and robust process evaluation, and retrospective data. In contrast to previous studies,[18] recruitment of a large purposive sample of family members who had a diverse range of views on organ donation was successful and target numbers were surpassed. A large group of patient and public representatives worked with researchers to co-produce the study, which has resulted in a more grounded interpretation of findings. Due to finite time and resources, we did not plan to interview NHS staff working in Welsh hospitals to ascertain their perspectives.

Small numbers, year on year fluctuations in potential deceased donors and consent rates, and health systems issues help explain why it has been difficult historically to establish if an opt-out system is the right option to introduce, and why increased consent rates have not yet translated into increased donor numbers. In Spain, it took 10 years following introduction of a soft opt-out system and further reorganisation to achieve 80% consent rates and increased donor numbers.[4-6] As a trial was not feasible, it was not possible to determine with certainty if the 60.8% (28/46) of families who supported deemed consent under the soft opt-out system would have given their consent anyway under the former opt-in system. Nor do we know for sure why overall consent rates dropped by 5% to 48.5% immediately prior to implementation of the Act. Nonetheless, since its introduction there has been a sustained recovery and a 12.5% improvement since 2013/14. One explanation is that there was a high profile coroner's case in Wales in December 2014, which received international attention.[19] Donor numbers across the UK fell following the news coverage (the only year on year fall in donor numbers in the UK in the last decade). One additional hypothesis is that introducing a soft opt-out system created harm that caused the pre-implementation drop. McCartney writing in the BMJ[9] suggested that '*some or many of those opting out may have been willing to donate freely but not under uncertain legislation'*. This was a view supported by patient and public representatives who co-produced the current study. In a separate analysis of media coverage,[20] we found a change to a more positive and supportive tone after 1st December 2015 when the soft opt-out was fully implemented that aligns with a general trend in improvements to consent rates.

Discounted over ten years, the costs were approximately £7.5 million to set up and maintain the infrastructure required to operate a soft opt-out system of organ donation, including business and system changes, the processing of opt-out requests, public communications, and evaluation. An increase of one donor per year with associated increases in organ transplantations, would generate sufficient benefits for a soft opt-out system to more than pay for itself.[21] The success of the soft opt-out system is however dependent on family members supporting their relative's donation decision made in life. Consent rates would have been higher if family members had consistently supported their relative's opt-in decision, although this would apply to both opt-in and opt-out systems. Assuming that the potential donor had not changed their decision from opt-in to opt-out, it appeared that some family members were not able to put their own negative views on organ donation aside, even when their position contradicted the majority family view that their relative had decided to donate their organs in life. Similarly, Shaw describes scenarios whereby family members objected to organ donation and deemed consent specifically.[22] The Act contains provision whereby a person can appoint a representative on the organ donor register to convey their donation decision when they die. Only 33 people had appointed a representative during the timeframe of the study (now risen to 35) and none were called upon during the first 18 months. If people are concerned that their relatives may not honour their donation decision, then appointing a representative may mitigate this relatively common situation. There is no appetite in Wales to introduce a hard opt-out system that removes the family from the decision-making process. Family members may however benefit from additional education to further clarify that it is not their decision to make and that their role is to support the donation decision made in life by their relative.

Our findings have important implications for other nations including the Netherlands, Scotland and England who have signalled an intention to implement a soft opt-out system.[23-25] SNODs were vital to the organ donation process and their role was highly valued by family members. Although implementation generally went smoothly, it was not possible for SNODs to obtain the required standard of evidence from family members to override a deceased person's donation decision and this requires revisiting. Investing sufficient resources (and correctly targeting) the media campaign, and mass retraining of large numbers of health care professionals staff is critical. Although generally successful at getting potential organ donors to change their behaviour and make their organ donation decision known, the Welsh media campaign paid no attention to the changing role of family members to one of supporting the donation decision of their relative made in life. In response, the Welsh Government has commissioned an additional post implementation media campaign focussing on the changed role of the family. Other nations considering a soft opt-out system should address the changed role of the family in a pre-implementation media campaign. A longitudinal study is now required to see if consent rates are maintained, continue to improve, and subsequently reach the national UK target of 80% by 2020,[26] and to monitor what happens to donor numbers. We also need to know and understand the specific reasons why 6% of people have opted out on the organ donor register. The rate of family overrides needs monitoring in the long-term to determine if the observed upward trend is a cause for concern that requires further investigation.

CONCLUSION

We found that introduction of the soft opt-out reversed a decline and subsequently improved consent rates for deceased organ donation, but in the short term the improvements were not statistically significant and had no impact on donor numbers. Whilst the soft opt-out has been most successful in getting potential organ donors to register or express their decision, or do nothing and have their consent deemed, it was primarily family member overrides and health systems issues that prevented support for their relative's opt-in donation decision and successful donation. Future media campaigns need to focus on changing the behaviours of family members to supporting their relative's donation decision made in life. NHS managers should focus on removing the health systems issues that thwart the legislative intention to improve consent and donation rates.

Given the growing worldwide interest in introducing opt-out systems and the unclear long-term impact on consent and donation rates these findings should be considered by policymakers who may assume that soft opt-out systems by themselves simply need more time to have a meaningful effect on donation numbers.

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List of Figures

Supplementary Files

Supplementary File 1. Summary of datasets and evidence.

Author contributions

Jane Noyes – Chief Investigator conceptualised the idea, put the team together, designed the study and procedures, and drafted manuscript.

Michael Stephens - Consultant Transplant and Organ Retrieval Surgeon, Clinical Lead for Transplantation, Cardiff and Vale Health Board - advised on key research team members and stakeholders to bring into the research team, proposed changes in the law and key research questions to address.

Karen Morgan – Formerly Regional Manager South Wales and South West, NHSBT and now Major Health Conditions Policy Team, Directorate of Health Policy, Health and Social Services Group, Welsh Government – advised on key changes to policy and practice, study design and processes, data collection tools and implementation of the study.

Phillip Walton – Regional Manager South Wales NHSBT advised on on changes to policy and practice, study design and processes, data collection tools, and implementation and analysis of the study.

Abigail Roberts – Specialist Nurse in Organ Donaiton NHSBT advised on the role of the Specialist Nurse in Organ Donation, study design and processes, data collection tools and implementation and analysis of the study.

Leah Mclaughlin – Research Officer – finalised study procedures and data collection processes, designed the study documentation and logos and supported production of applications to the NHS REC and NHSBT R&D committees, undertook fieldwork and analysed data.

Susanna Madden and Rebecca Curtis – Statisticians at NHSBT - undertook the statistical analysis.

All authors contributed to drafting and agreed the final submitted manuscript.

Acknowledgments

Fiona Wellington: Head of Operations NHSBT for supporting the study. Christian Brailsford: NHSBT provided advice and support to agree a mutual data sharing agreement and negotiate NHS ethics and NHSBT RINTAG and NHSBT R&D processes. Pat Vernon (Policy Lead Welsh Government), Ian Jones (Research and Evaluation Lead), Caroline Lewis (Organ Donation Policy Manager) provided a Government perspective and shared research carried out prior to implementation of the Act.

Donald Fraser: Lead of the Wales Kidney Research Unit supported development of the funding application and served as independent Chair of the steering group.

Carol Williams for undertaking Welsh language and some English interviews. Jo Mitchell for providing administrative support and transcription.

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Patient and public representatives: Jeanette Bourne and CRUSE Bereavement Care Cymru, who provided leaflets signposting bereavement support for participants. Sarah Thomas Centre for Sight and Sound, Janet Thickpenny Big Lottery, Gethin Rhys Churches Together in Wales, Michael Rhys, Janet Williams and Gloria Owen.

Maria Mesa Women Connect First, Roon Adams Race Equality First, Michael and Jess Houlston Donor Family Network, Maria Battle Chair of Cardiff and Vale University Health Board, Anna Bates Believe, Llanelli Multicultural Network, Rita's Café.

Bethan Moss Team Manager for reviewing the NHSBT anonymised database and supporting data analysis.
Lisa Welsh, team leader, Donor Records Department for ensuring packs, envelopes and consent forms were included in donor packs for the duration of the study. Keeping the research team updated and following up with postal follow ups.
Gill Drisma, Manager Donor Records Department, NHSBT for helping set up the data collection process and ensuring support staff were kept up to date of the study.
Lynne Woolcocks, Regional Office Manager, South Wales & South West Organ Donation and Transplantation for supporting the postal follow ups and co-ordinating with DRD to ensure all families had opportunity to participate in the study.

A special thank you to all the families. Thank you for agreeing to share your stories so that we could learn from your experiences.

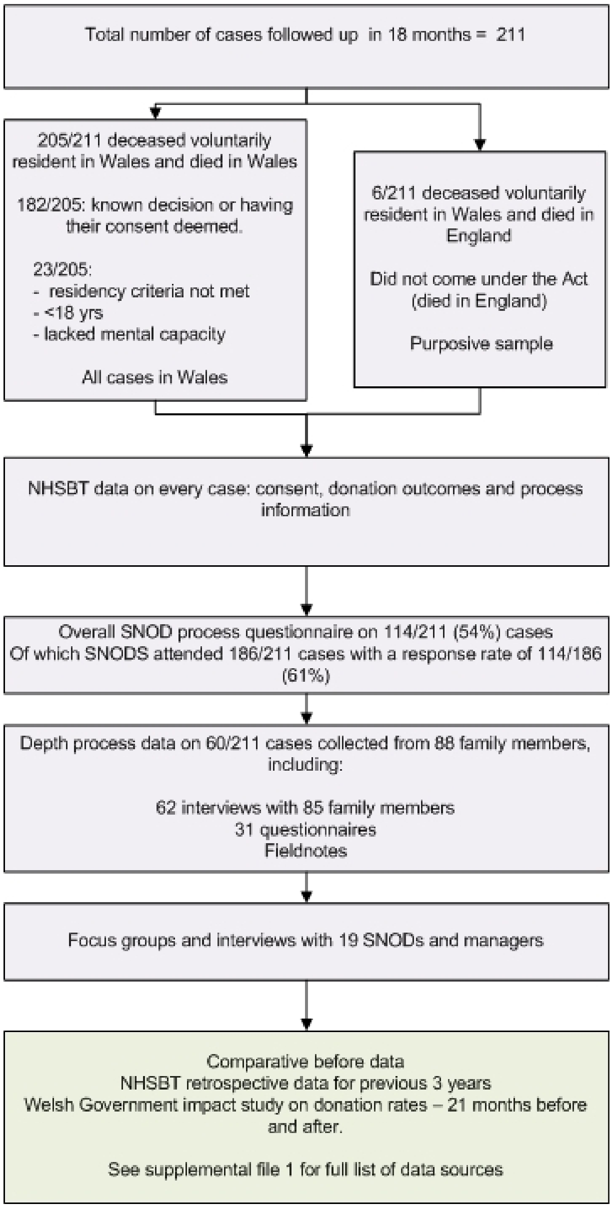

Figure 1. Study design, recruitment and response rates.

95x188mm (96 x 96 DPI)

Supplementary File 1. Summary of datasets and evidence.

	Dataset/Evidence	**Content**
		Anonymous data shared by NHSBT under data sharing agreement
1	**Anonymised NHSBT Log**	The log records details of all approach conversations that Specialist Nurses in Organ Donation had with a potential donor family for whom the Act applied over the data collection period (18 months) 01/12/15 - 31/05/17. It was created specially to capture specific details of the consent conversation after the law changed in Wales. The log includes: 1. A record of whether the deceased died via a Donation by Brain Stem Death (DBD) or Donation by Circulatory Death (DCD). 2. The deceased person's registered status on the Organ Donor Register (ODR) – Registered In/out or no registration found. 3. Type of Consent – Organ Donation Register In/Out, Expressed Consent In/Out, Deemed Consent and family consent (for those who did not fulfil the criteria to have their consent deemed). 4. Patients expressed decision – donate all organs, does not want to donate, no decision made. 5. Who the SNOD had the conversation with. 6. Did the family accept the known decision of the deceased person. 7. Reason why family objected to the known decision or the deemed consent. 8. If organ donation proceeded – the comments in number 11 will document if the donation stood down due to a medical reason or via the influences of the family, see number 11. 9. Who undertook the donation conversation. 10. Did family know about the Welsh Legislation. 11. Comments (to include evidence/information provided by families who are unable to support known decision/deemed consent). 12. Feedback/additional training requirements to staff – did this particular case highlight any areas for further professional development training. Descriptive statistics report totals for categorical data.
2	**Summary statistics from NHSBT for the 18 month data collection window for Wales only.**	NHSBT summary of descriptive statistics specially prepared for the research team to cover the data collection window (01/12/15-31/05/17). Data has been obtained from the Potential Donor Audit (PDA) and Referral Record and includes summary data on: organ donation registration; consent and deemed consent numbers; age range; ethnicity and reasons why donation not proceeded.
		Routinely collected and publicly available NHSBT data
3	**Publicly Available NHSBT Annual Activity Reports (UK). Continuous annual audit.**	NHSBT Annual Activity Reports run from 01st April – 31st March and are available online for current and previous years. Welsh data mapped onto this study includes: Organ Donation Registration data; Number of deceased donors and Consent rates.

4	**Publicly Available NHSBT Annual PDA Reports (UK). Continuous annual audit.**	NHSBT Annual PDA Reports run from 01st April – 31st March and are available online for current and previous years. Includes UK figures for: Reasons why consent not given/decision not supported Age, Ethnicity, gender of donors.
5	**Organ Donation Register UK.**	The UK organ donor register was amended in July 2015 to allow for opt-out registrations. People have the opportunity to Opt-in, Opt-Out and appoint a representative. Registration behaviour figures and trends were used to contextualise study findings.
		Publicly Available Welsh Government Commissioned Research
6.	**Impact Evaluation**	Welsh Government commissioned – looked at donation trends and numbers.
7.	**Focus groups with SNODS**	Welsh Government commissioned three sequential focus groups with SNODS, before, immediately after implementation and a year after the changes were introduced. Final focus group findings shared ahead of publication.
8.	**Omnibus Surveys**	Welsh Government commissioned 12 sequential public opinion surveys undertaken with the Welsh public in the years before and after the law changed. Wave 10 of the survey focused on monitoring awareness levels and understanding of the change in law and included additional questions to measure awareness and recall of publicity campaign material. Wave 11 and 12 focused on awareness and understanding as well as attitudes and behaviour.
9.	**Literature reviews**	Systematic reviews of the literature on family attitudes to organ donation and reasons why donation is declined.
		Additional data collection by the research team
10.	**Anonymous Family, Questionnaire FORM C.**	Families are sent a questionnaire capturing basic information on their understanding of the changes and their feelings about supporting their loved one's donation decision. Appendix 3. FORM C: Questionnaire completed by family members/close friends.
11	**Interviews with families**	Depth Interviews with 85 family members of 60 cases to explore their views on organ donation, the Act, the media campaign and their donation experience.
12	**Anonymous SNOD Questionnaire Form B.**	SNODS completed a questionnaire after each approach conversation to document information on the family's understanding of their role, their attitudes and behaviours and the outcome of the process.
13 13.1	**Focus Groups with SNODS.** **Interviews with Specialist Requesters.**	Focus groups with 19 key SNODS, managers and specialist requesters in the North West team and South Wales team to explore SNODS experiences of implementing the act in practice.

13.2	**Interviews with team and regional managers**	
14	**Field Notes from interviews**	Researchers and transcribers document their thoughts and views from interview.
15	**Interim feedback from Patient and Public representatives, (PPI's), SNOD's, Managers, NHSBT, NHS, Clinical Leads Organ donation, and other key stakeholders.**	A two day interim findings conference was held in Birmingham on the 9th and 10th November 2016. The purpose was to present interim findings to a key group of 50 NHSBT staff, NHS staff, Welsh Government representatives and PPIs. Feedback was collected on 10 presentations reviewing the various datasets thus far.
16	**Research team perspectives**	Weekly team meetings and monthly data analysis meetings are recorded to capture the ongoing analysis and interpretation of data and to put findings into wider context and highlight issues needing further attention.
		Additional contextual data produced by the research team to situate the evaluation findings
17	**Update of the literature**	Update of the systematic reviews in 9.
18	**Discourse Analysis of the press & media**	The discourse analysis will include the public media campaign, press articles and news stories promoting the changes.

BMJ Open

Short-term impact of introducing a soft opt-out organ donation system in Wales: Before and after study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025159.R1
Article Type:	Research
Date Submitted by the Author:	15-Nov-2018
Complete List of Authors:	Noyes, Jane; Bangor University, School of Social Sciences Mc Laughlin, Leah; School of Social Sciences Morgan, Karen ; Welsh Government, Major Health Conditions Policy Team Walton, Philip; NHS Blood and Transplant , Organ Donation Department, Unit 3 Cae Gwyrdd, Greenmeadow Springs Business Park, Tongwynlais, Cardiff, UK. Curtis, Rececca ; NHS Blood and Transplant Organ Donation and Transplantation Directorate, Statistics and Clinical Studies Madden, Susanna ; NHS Blood and Transplant Organ Donation and Transplantation Directorate, Statistics and Clinical Studies Roberts, Abigail; NHS Blood and Transplant Stephens, Michael; Cardiff and Vale University Health Board, University Hospital of Wales, Department of Nephrology and Transplantation, Heath Park, Cardiff, UK.
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health policy, Evidence based practice
Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

TITLE PAGE

Short-term impact of introducing a soft opt-out organ donation system in Wales: Before and after study.

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Abstract

Objectives
To determine the short-term impact of the introduction of a soft opt-out system of organ donation on consent rates and organ donor numbers.
Design. Before and after observational study using routinely collected data**.**
Setting: NHS Blood and Transplant and NHS hospitals in Wales.
Participants. 205 potential organ donor cases in Wales.
Interventions: The Act and implementation strategy.
Primary and secondary outcomes: Consent rates at 18 months post implementation compared with 3 previous years, and numbers of organ donors during 21 months before and after implementation. Changes in organ donor register activity post implementation for 18 months.
Results: The overall consent rate 18 months post implementation was 60.9% (125/205), showing a recovery from 48.5% in 2014/15 but not significantly different from the three preceding years. 22.4% (46/205) were deemed consented donors: consent rate 60.8% (28/46). Deceased donors did not increase:101 compared with 104, 21 months pre and post implementation. Organ donation registration increased from 34-38% with 6% of the population opting out of organ donation on the register.
Conclusion: Consent rates increased but not significantly. The long-term impact on donor numbers is unclear. Concerns about a potential backlash and mass opting out were not realised. The move to a soft opt-out system has not resulted in a step change in organ donation behaviour, but can be seen as the first step of a longer journey. Policymakers should not assume that soft opt-out systems by themselves simply need more time to have a meaningful effect. Ongoing interventions to further enhance the soft-opt out system, the health system within which it is implemented and the public's understanding of organ donation are needed to reach the target of 80% consent rates by 2020. Further longitudinal studies are required to monitor if positive trends in consent rates translate to increased donor numbers.

Strengths and weaknesses of the study

- Routinely collected data were analysed for all potential organ donor cases.
- A large group of patient and public representatives worked with researchers to co-produce the study.
- The study is limited to establishing short-term impacts and a longitudinal study with larger numbers is required to determine changes over time.

Original Protocol

Noyes J, Morgan K, Walton P, Roberts A, Mclaughlin L, Stephens M. Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: mixed-method study protocol. **BMJ Open.** 2017 Oct 12;7(10):e017287. doi: 10.1136/bmjopen-2017-017287

Funding statement

The study was funded by Health and Care Research Wales. Project Reference 1129.

Competing interests statement

There are no known competing interests.

Patient consent

Article contains no identifiable personal medical information.

Data sharing statement

Additional unpublished data are not publicly available.

INTRODUCTION

Around 6500 people are waiting for organ transplants in the United Kingdom (UK).[1] Organ transplantation is cost-effective and improves quality of life for recipients.[2] Organ donation consent rates in the UK need to improve to keep up with demand for transplants.[3]

Under the opt-in system in Wales, consent rates for deceased organ donation ranged between a high of 53.6% to a low of 48.5% between 2013-2015.[4] In contrast consent rates in some other European countries are much higher. For example, in Spain consent ranges from 80-85% in an opt-out system in which all citizens are automatically assumed to consent to organ donation unless they choose to state otherwise. [5]

The British Medical Association, patient groups and newspapers[6-7] have lobbied for the introduction of an opt-out system to replace the current opt-in system in the respective UK nations (England, Scotland, Wales, Northern Ireland). The UK nations have separate, and in the case of Scotland, Wales and Northern Ireland devolved, responsibilities for health. There are two types of 'opt-out' system: a 'hard' opt-out where the family are not consulted or a 'soft' opt-out where the family are consulted. Opinion is starkly divided as to the benefits of introducing either form of opt-out system of organ donation compared with reorganisation of the current opt-in system to increase consent rates.[8-9] A comparison of the opt-in and soft opt-out default systems can be found in Table 1. Box 1 contains key operational definitions.

Table 1. Comparison of the previous opt-in and new soft out-opt system in Wales.

	Decision Type			
	Active	Passive	Geographical reach	Role of family
Former Opt-in system	Expressed decision: Register to opt in on the organ donor register Verbally tell a relative or friend you want or do not want to be a donor Write telling a relative or friend you want or do not want to be a donor Nominate a representative to make the decision for you. (Nowhere to record this decision)	Do nothing and remain a non-donor	UK wide	To give consent for organ donation
New Opt-Out System in Wales	Expressed decision: Register to opt-in on the organ donor register Verbally tell a relative or friend you want to be a donor Write telling a relative or friend you want or do not want to be a donor Register to opt-out on the organ donor register Appoint a patient representative on the organ donor register to make the decision for you	Do nothing and remain as a donor (Deemed consent)	Wales only Welsh citizens have to die in Wales for the soft-opt out to apply. If they die in England the opt-in system applies.	To support the donation decision of their relative made in life

Box 1. Additional key terms and operational definitions

Key term	Definition
Opt-in organ donation system	The default is to be a non-donor unless an individual actively registers or expresses to be an organ donor.
Opt-out organ donation system	The default is presumed consent (called deemed consent in Wales) to organ donation, unless an individual actively opts out.
Hard opt-out organ donation system	The family are not consulted
Soft opt-out organ donation system	The family are consulted
Soft opt-out eligibility criteria Wales	Over 18 years, voluntarily resident in Wales, mental capacity, die in Wales.
Expressed decision	A person may register their decision on the organ donor register or convey it verbally or in writing to family members (see Table 1 for options available under the different systems).
Organ Donor Register	Under the former opt-in system individuals could only opt in to be a donor on the register. With the introduction of the soft opt-out system in Wales the register was amended so that individuals can opt in or opt out of organ donation on the register, and appoint a representative to convey the decision for them.
Presumed/Deemed consent	The terms are interchangeable, but in Wales the term used is deemed consent. A person* who has not actively expressed their organ donation decision during

	life is considered to have no objection to organ donation and their consent can be deemed. *Eligibility criteria apply.
Known donation decision	The potential organ donor has made their decision known during life time by either registering it on the organ donation register or conveying it verbally or in writing to family members/close friends.
Family consent in the soft opt-out system	Family consent is for children under 18 years, and for potential organ donors who do not meet residency criteria or lack mental capacity.
Organ donation decision overrides	Under the new soft-opt out system, family members are expected to support the organ donation decision of their relative made in life. To override their relative's decision family members should provide witnessed written evidence or a witnessed conversation that the potential organ donor had changed their mind and opted for a different donation decision (the last known decision).

Following an extensive public consultation, the Human Transplantation (Wales) Act 2013 introduced a soft opt-out system of organ donation, which was fully enacted on 1st December 2015.[10] The purpose of the Act is to make it easier for people to donate their organs to benefit patients. The primary aim is to increase consent rates. In the Welsh soft opt-out system unless the deceased person has expressed a decision in life (either for or against being be an organ donor) it will be assumed that they have no objection to organ donation and their consent can be deemed. Family members are expected to support the donation decision made by their relative in life.

How the intervention is intended to work

A detailed description of the components and how the intervention is intended to work can be found in the study protocol.[4] In summary, the Act, media campaign and implementation strategy were conceptualised as a complex behaviour change intervention. The Act changed the principles of consent to deceased organ donation from an opt-in to a soft opt-out system for adults 18 years or over; voluntarily resident for 12 months or more in Wales; who have not made an expressed decision regarding organ donation; and is competent to understand the notion of deemed consent. The individual must also die in Wales for the Act to apply. In addition to the public media campaign, there was an accompanying implementation strategy for National Health Service (NHS) and NHS Blood and Transplant (NHSBT) staff, which required amending clinical protocols and procedures and retraining large numbers of staff and all Specialist Nurses in Organ Donation (SNODs) covering Wales. The success of the Act depended on behaviour change of the public and professionals. The theory is that the neutral media campaigns supporting implementation will facilitate the behaviours in Welsh citizens outlined in Box 2.

Box 2. Intended behaviours of the citizens of Wales under the soft opt-out system.[4]

- opt-in or opt-out on the organ donor register (registered decision), with the option of appointing a patient representative
- discuss opt-in or opt-out donation decision with families and friends (express decision)
- do nothing and it will be assumed that the person does not object to organ donation (deemed consent)
- families will put aside their own views on donation and respect the decision of the deceased person made in life.

There are few examples where soft opt-out systems have been implemented in the context of rigorous research and no examples of process evaluations with family members who were approached about organ donation when a change to a soft opt-out system has been implemented. The aim of this study was to determine the short-term impact of the introduction of a soft opt-out system of organ donation on consent rates and organ donor numbers. Elsewhere we report the process evaluation findings of the nurse-led implementation of the soft opt-out system that help contextualise and explain the initial impacts.[11]

METHODS

We worked with NHSBT to analyse a bespoke dataset of routinely collected data (including the Potential Donor Audit) on all potential organ donor cases, and organ donor registration activity for 18 months after the 1st December 2015 when the soft opt-out was implemented in Wales, compared with up to three years pre-implementation.[4] Welsh Government shared comparative figures on numbers of deceased donors for 21 months before and after implementation.[12] For the purposes of his study a potential organ donor was defined as a patient who is eligible for organ donation and whose family is approached for a formal organ donation discussion.

Primary and secondary outcomes: Consent rates and numbers of organ donors compared with previous years. Changes in organ donor register activity post implementation for 18 months.

Participants. All 205 potential organ donor cases in Wales were included.

Data collection and analysis

NHSBT routinely collected data on each case

Retrospective data on consent rates, donor numbers and transplant numbers is routinely collected for each financial year (12 months). We worked with NHSBT to analyse prospective data for 18 months post implementation on 1st December 2018. These data covered 1 full financial year and a period of months from two further financial years. NHSBT statisticians compiled summary reports of descriptive statistics for the 18 month post-implementation period and provided reports of comparative retrospective data, and statistical significance. A chi-squared test was used to determine whether there was a statistical difference in overall consent rates between the 3 years prior to the introduction of the soft opt-out and deemed consent compared to the 18-months following the introduction of the soft-optout and deemed consent (Table 2).[13] Data were grouped by mode of consent (expressed and registered opt-in and opt-out; deemed, and family consent), and total numbers of families approached. Data on proceeding donors and transplants were also compared. In addition, Welsh Government shared their analysis of numbers of organ donors for 21 months pre and post implementation.

Ethics

The protocol was approved on 23/10/15 by NHSBT Research, Innovation and Technology Advisory Group (RINTAG). This approval included agreement to share anonymised NHSBT data. The study was approved by the Wales Research Ethics Committee 5 NHS research ethics committee (IRAS number 190066; Rec Reference 15/WA/0414 on 25/11/2015) and the NHSBT Research and Development Committee (NHSBT ID: AP-15-02 on 24/11/2015). Bangor University was the study sponsor.

Patient and Public Involvement

This was a co-productive study with extensive patient and public involvement of over 50 people and organisations in the design, analysis and interpretation of data. A 2-day residential meeting and an end of study event were convened to discuss and interpret findings. Patient and public involvement was most evident in the design and conduct of the associated process evaluation. A detailed report evaluating the impact of the co-productive approach and the contribution of patient and public representatives is published elsewhere.[14]

RESULTS

There were 205 deceased donors in Wales of which 88.7% (182/205) met the criteria for a known decision (ie they expressed a decision in life (either for or against being be an organ donor) or having their consent deemed (Figure 1 and Table 2). The remaining 11.2% (23/205) cases met the criteria for the 'family' mode of consent as the deceased person was a child, lacked mental capacity or did not meet residency criteria. The consent rate for all modes of consent was 60.9% (125/205), showing a recovery from the dip to 48.5% in 2014/15. Compared to the consent rates in the 3 full financial years prior to the introduction of the soft opt-out and deemed consent there was a significant difference in the consent rates (chi-squared p-value=0.03) but this highlighted that the dip in 2014/15 was significantly lower than other years rather than deemed consent having significantly improved the consent rate. The consent rate in 2012/13 (50.3%, 95%CI: 42.6% - 58.0%) and 2013/14 (91%, 95% CI: 46.3% - 61.3%) were similar to the consent rate under the soft opt-out system that introduced deemed consent (60.9%, 95% CI: 54.3% - 67.7%).

When family consent was excluded, the consent rate for 182/205 cases that met the criteria for a known decision or deemed consent was 64.2%. Just over 22% (46/182) of cases were deemed consented donors with a consent rate 60.8% (28/46).

Seventy-nine percent (162/205) had registered or expressed a decision, of which 62.4% (128/205) of cases had registered or expressed their decision to opt-in. Fifty-seven percent (73/128) registered to opt-in on the organ donor register, and 22.6% (29/128) verbally expressed to opt-in with their families during their lifetime. Just over 16.5% (34/205) opted-out: 8/34 opted-out on the organ donor register and 26/34 expressed to their families that they wanted to opt-out.

Family members still overrode 15.1% (31/205) opt-in decisions to donate, including 16.4% (12/73) organ donor registered opt-in decisions; 3.4% (1/29) verbally expressed opt-in decisions, and 39.1% (18/46) deemed consents.

Of the 125/205 cases where consent to deceased donation was supported by family members, 69.6% (87/125) proceeded to donation. The number of deceased donors remained relatively static (101 compared with 104 21 months pre and post implementation).[12] The number of potential donors however fell over this period, so although the overall donor numbers stayed roughly the same, this was in the context of fewer potential donors. Finally, organ donation registration increased from 34-38%. As of June 2017, 1,181,709 people in Wales had opted-in and 176,011 opted-out, which is 6% of the population and less than the Government anticipated would opt-out.

Families approached by subsequent mode of consent: Deceased organ donation Wales	**Retrospective before**			**Prospective after implementation of the soft opt-out on 1st December 2015**			
	April 2012 – March 2013 12 months	**April 2013 – March 2014 12 months**	**April 2014-March 2015 12 months**	**Dec 2015- Mar 2015 4 months**	**April 2016 – March 2017 12 months**	**April 2017 May 2017 2 months**	**Total Dec 2015- May 2017 18 months**
Total families approached: number of cases	**161**	**169**	**153**	**54**	**141**	**10**	**205**
Total cases that met the criteria for a known decision or having their consent deemed. Excludes family consent (child, not Welsh resident, lacks mental capacity)	**N/A**	**N/A**	**N/A**	**51/54 (94.4%)**	**124/141 (87.9%)**	**7/10 (70.0%)**	**182/205 (88.8%)**
Expressed consent:	56/161 (34.8%) Registered opt in on ODR 48/56 (85.7%) Verbally expressed opt in 7/56 (12.5%) Other 1/56 (1.8%)	62/169 (36.7%) Registered opt in on ODR 52/62 (83.9%) Verbally expressed opt in 10/56 (17.8%)	48/153 (31.4%) Registered opt in on ODR 43/48 (89.6%) Verbally expressed opt in 5/48 (10.4%)	21/51 (41.2%)	76/124 (61.3%)	5/7 (71.4%)	**102/205 (49.7%)** **Registered opt in on ODR** **73/102 (71.6%)** **Verbally expressed opt in** **29/102 (28.4%)**
Deemed consent	N/A	N/A	N/A	13/51 (25.5%)	31/124 (25.0%)	2/7 (28.6%)	**46/205 (22.4%)**
Family consent	105/161 (65.2%)	107/169 (63.3%)	105/153 (68.6%)	3/51 (5.9%)	17/124 (13.7%)	3/10 (30.0%)	**23/205 (11.2%)**
Total patient opt-outs:	**N/A**	**N/A**	**N/A**	**17/51 (33.3%)**	**17/124 (13.7%)**	**0**	**34/205 (16.5%)**
Registered opt out on ODR	N/A	N/A	N/A	3/17 (17.6%)	5/124 (4.03%)	0	**8/34 (23.5%)**
Verbally expressed opt out	N/A	N/A	N/A	14/17 (82.3%)	12/124 (9.7%)	0	**26/34 (76.5%)**
Mode of consent ascertained (consent rate)							
Total consent ascertained*	**81/161 (50.3%)**	**91/169 (53.8%)**	**70/153 (45.8%)**	**29/54 (53.7%)**	**90/141(63.8%)**	**6/10 (60.0%)**	**125/205 (60.9%)**
Total consent for cases that met the criteria for a known decision or having their consent deemed.	**N/A**	**N/A**	**N/A**	**27/51 (52.9%)**	**85/124 (68.5%)**	**5/7 (71.4%)**	**117/182 (64.2%)**
Expressed consent	48/56 (85.7%)	53/62 (85.5%)	37/48 (77.1%)	18/21 (85.7%)	66/76 (86.8%)	5/5 (100%)	**89/102 (87.2%)**
Deemed consent	N/A	N/A	N/A	9/13 (69.2%)	19/31 (61.2%))	0	**28/46 (60.8%)**
Family consent	33/105 (31.4%)	38/107 (35.5%)	33/105 (31.4%)	2/3 (66.6%)	5/ 17 (29.4%)	1/3 (33.3%)	**8/23 (34.7%)**
Overrides by family members							
Total overrides by family members	**8/161 (5%)**	**9/169 (5.3%)**	**11/153 (7.2%)**	**7/54 (12.9%)**	**22/141 (29.1%)**	**2/10 (20%)**	**31/205 (15.1%)**
ODR overrides	8/48 (16.7%)	7/52 (13.5%)	10/43 (23.3%)				**12/73 (16.4%)**
Other expressed overrides	0	2/10 (20%)	1/5 (20%)				**1/29 (3.4%)**

Deemed consent	N/A	N/A	N/A				**18/46 (39.1%)**
Proceeding donors by mode of consent							
Expressed consent: Verbal or ODR registration	26/48 (51.4%)	33/53 (62.2%)	28/37 (75.7%)	13/18 (72.2%)	43/66 (65.1%)	4/5 (80.0%)	**60/89 (67.4%)**
Deemed consent	N/A	N/A	N/A	9/9 (100%)	11/19 (57.9%)	0	**20/28 (71.4%)**
Family consent	24/33 (72.3%)	21/38 (55.3%)	26/33 (78.8%)	2/2 (100%)	4/5 (80.0%)	1/1 (100%)	**7/8 (87.5%)**
Total	**52/81 (64.2%)**	**54/91 (59.3%)**	**60/70 (85.7%)**	**24/29 (82.7%)**	**58/90 (64.4%)**	**5/6 (83.3%)**	**87/125 (69.6%)**
Organs donated by mode of consent							
Expressed consent: Verbal or ODR registration	89	108	100	44	136	17	**197**
Deemed consent	N/A	N/A	N/A	31	39	0	**70**
Family consent	88	69	78	12	10	4	**26**
Total	**177**	**177**	**178**	**87**	**185**	**21**	**293**
Organs transplanted by mode of consent							
Expressed consent: Verbal or ODR registration	83	97	87	36	116	15	**167**
Deemed consent	N/A	N/A	N/A	26	33	0	**59**
Family consent	82	63	62	12	9	2	**23**
Total	**165**	**160**	**149**	**74**	**158**	**17**	**249**
Comparative total consent ascertained rate for England	57.9%	59.6%	58.5%		62.5%		
Comparative donor numbers* Figures shared by Welsh Government for 21 months pre and post[8] *Before and after change not statistically significant	21 months pre - 101			21 months post- 104			

Table 2. Before and after results.

DISCUSSION

Consent rates in Wales have improved but the differences are not yet statistically significant. It is too early to tell if the soft-opt out system will be successful in further increasing consent rates. It is clear from the analysis that the move to a soft opt-out system has not resulted in a step change in organ donation behaviour, but is the first step of a longer journey.

Although there was general support for the soft opt-out system, decisions made by the citizens of Wales during life were not consistently supported as intended by family members in death. The success of the soft opt-out system is dependent on family members supporting their relative's donation decision made in life. Consent rates would have been higher if family members had consistently supported their relative's opt-in decision, although this would apply to both opt-in and opt-out systems. Whilst acknowledging that numbers are too small at this stage to undertake a more sophisticated statistical analysis, and the introduction of new modes of consent (with new potential opportunity to override) make direct comparisons difficult to interpret, there was an observed upward trend in family overrides following introduction of the soft-opt out system (Table 2). For the three years prior to implementation family overrides ranged from 5-7.2%. Post implementation it was 15.1% over 18 months, and 29.1% in 2016/17. Some of the increase can be explained by the introduction of deemed consent, which provided a new opportunity to override that did not exist before. The reasons why family members still override their relative's opt in decision are numerous and complex and our process evaluation published elsewhere provides a detailed explanation to contextualise the findings reported here.[11] Importantly, process evaluation findings show that SNODs were not able to establish the required standard of evidence to override an opt in donation decision made in life. They accepted a lesser standard of evidence and donation did not proceed.

Assuming that the potential donor had not changed their decision from opt-in to opt-out, it appears that some family members were not able to put their own negative views on organ donation aside. Similarly, Shaw describes scenarios whereby family members objected to organ donation and deemed consent specifically.[15] We found that family members have yet to accept 'doing nothing' (deemed consent) as a positive decision in support of organ donation. The fact that the consent rate obtained via deemed consent is the same as the overall consent rate is an important and reassuring finding. There was some support for Shaw's assumption that families are more likely to overrule a consent that is merely presumed (the equivalent of deemed consent in Wales) in that post implementation family support for an expressed decision made in life (87.2% 89/102) was higher than for a deemed decision (60.8% 28/46).[16] Nonetheless, post implementation, overall consent rates were brought down by the low rate of family consent for children, and potential donors who did not have mental capacity or meet residency criteria (34.7% 8/23).

The Act contains provision whereby a person can appoint a representative on the organ donor register to convey their donation decision when they die. Only 33 people had appointed a representative during the timeframe of the study (now risen to 35) and none were called upon during the first 18 months. If people are concerned that their relatives may not honour their donation decision, then appointing a representative may mitigate this relatively common situation. There is no appetite in Wales to introduce a hard opt-out system that removes the family from the decision-making process. Family members may however benefit from additional education to further clarify that it is not their decision to make and that their role is to support the donation decision made in life by their relative. The rate of family overrides needs monitoring in the long-term to determine if the observed upward trend is a cause for concern that requires further investigation.

At an individual potential donor level it has been made easier to convey a decision to donate organs. Sixty percent of cases were either registered on the organ donor register or had discussed their donation decision with family member(s), and as of March 2018, 39% of the population are registered to opt in to donate on the organ donor register. Any fears that introducing an opt-out system would cause a backlash by somehow changing the concept of the 'gift' of organ donation has not been realised. Only a relatively small number of people have thus far opted out (6%) on the organ donor register, and people are still opting in more than previously.

A more complex analysis was not performed given the small numbers involved in the first 18 months following introduction of the soft opt-out system and deemed consent in Wales. Small numbers, year on year fluctuations in potential deceased donors and consent rates, and health systems issues help explain why it has been difficult historically to establish if an opt-out system is the right option to introduce, and why increased consent rates have not yet translated into increased donor numbers. In Spain, it took 10 years following introduction of a soft opt-out system and further reorganisation to achieve 80% consent rates and increased donor numbers.[4-6] As a trial was not feasible, it was not possible to determine with certainty if the 60.8% (28/46) of families who supported deemed consent under the soft opt-out system would have given their consent anyway under the former opt-in system. Nor do we know for sure why overall consent rates dropped by 5% to 48.5% immediately prior to implementation of the Act. Nonetheless, since its introduction there has been a sustained recovery and a 12.5% improvement since 2013/14. One explanation is that there was a high profile coroner's case in Wales in December 2014, which received international attention.[17] Donor numbers across the UK fell following the news coverage (the only year on year fall in donor numbers in the UK in the last decade). One additional hypothesis is that introducing a soft opt-out system created harm that caused the pre-implementation drop. McCartney writing in the BMJ[9] suggested that '*some or many of those opting out may have been willing to donate freely but not under uncertain legislation*'. This was a view supported by patient and public representatives who co-produced the current study. In a separate analysis of media coverage,[18] we found a change to a more positive and supportive tone after 1st December 2015 when the soft opt-out was fully implemented that aligns with a general trend in improvements to consent rates.

Discounted over ten years, the costs were approximately £7.5 million to set up and maintain the infrastructure required to operate a soft opt-out system of organ donation, including business and system changes, the processing of opt-out requests, public communications, and evaluation. An increase of one donor per year with associated increases in organ transplantations, would generate sufficient benefits for a soft opt-out system to more than pay for itself.[19] With this in mind, further attention needs to be given to reducing the number of consented donors who do not proceed to donation. During the 18 months post implementation around 30% of consented donors did not proceed. Our process evaluation sheds more light on the issues that prevent donation proceeding, some of which are amenable to intervention to reduce this figure.

Our findings have important implications for other nations including the Netherlands, Scotland and England who have signalled an intention to implement a soft opt-out system.[20-23] Our process evaluation makes clear that there are many different issues that impact on whether or not a family supports their relative's organ donation decision, which could be addressed. A longitudinal study is required to see if consent rates are maintained, continue to improve, and subsequently reach the national UK target of 80% by 2020,[24] and to monitor what happens to donor numbers. Having accumulated more data since the conclusion of this study, other NHSBT studies are underway which are looking into this. We also need to know and understand the specific reasons why 6% of people have opted out on the organ donor register.

CONCLUSION

We found that introduction of the soft opt-out reversed a decline and subsequently improved consent rates for deceased organ donation, but in the short term the improvements were not statistically significant and had no impact on donor numbers. Whilst the soft opt-out has been most successful in getting potential organ donors to register or verbally express their decision, or do nothing and have their consent deemed, it was primarily family member overrides and health systems issues that prevented support for their relative's opt-in donation decision and successful donation.

Given the growing worldwide interest in introducing opt-out systems and the unclear long-term impact on consent and donation rates these findings should be considered by policymakers who may assume that soft opt-out systems by themselves simply need more time to have a meaningful effect on donation numbers.

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Author contributions

Jane Noyes – Chief Investigator conceptualised the idea, put the team together, designed the study and procedures, and drafted manuscript.

Michael Stephens - Consultant Transplant and Organ Retrieval Surgeon, Clinical Lead for Transplantation, Cardiff and Vale Health Board - advised on key research team members and stakeholders to bring into the research team, proposed changes in the law and key research questions to address.

Karen Morgan – Formerly Regional Manager South Wales and South West, NHSBT and now Major Health Conditions Policy Team, Directorate of Health Policy, Health and Social Services Group, Welsh Government – advised on key changes to policy and practice, study design and processes, data collection tools and implementation of the study.

Phillip Walton – Regional Manager South Wales NHSBT advised on on changes to policy and practice, study design and processes, data collection tools, and implementation and analysis of the study.

Abigail Roberts – Specialist Nurse in Organ Donaiton NHSBT advised on the role of the Specialist Nurse in Organ Donation, study design and processes, data collection tools and implementation and analysis of the study.

Leah Mclaughlin – Research Officer – finalised study procedures and data collection processes, designed the study documentation and logos and supported production of applications to the NHS REC and NHSBT R&D committees, undertook fieldwork and analysed data.

Susanna Madden and Rebecca Curtis – Statisticians at NHSBT - undertook the statistical analysis.

All authors contributed to drafting and agreed the final submitted manuscript.

Acknowledgments

Fiona Wellington: Head of Operations NHSBT for supporting the study. Christian Brailsford: NHSBT provided advice and support to agree a mutual data sharing agreement and negotiate NHS ethics and NHSBT RINTAG and NHSBT R&D processes. Pat Vernon (Policy Lead Welsh Government), Ian Jones (Research and Evaluation Lead), Caroline Lewis (Organ Donation Policy Manager) provided a Government perspective and shared research carried out prior to implementation of the Act.

Donald Fraser: Lead of the Wales Kidney Research Unit supported development of the funding application and served as independent Chair of the steering group.

Carol Williams for undertaking Welsh language and some English interviews. Jo Mitchell for providing administrative support and transcription. Barbara Neukirchinger (intern), Natalie Roberts (intern).

North West NHSBT Team: Kathryn Alletson, Ben Armstrong, Adam Barley, Helen Bullock, Angela Campion-Sheen, Laura Ellis-Morgan, Rebecca Gallagher, Sharon Hallam, Phil Jones, Andrew Mawson, Abi Roberts, Tracey Rhodes, Jane Monks, Emma Thirlwall, Dawn Lee, Nicky Hargreaves, Sue Duncalf.

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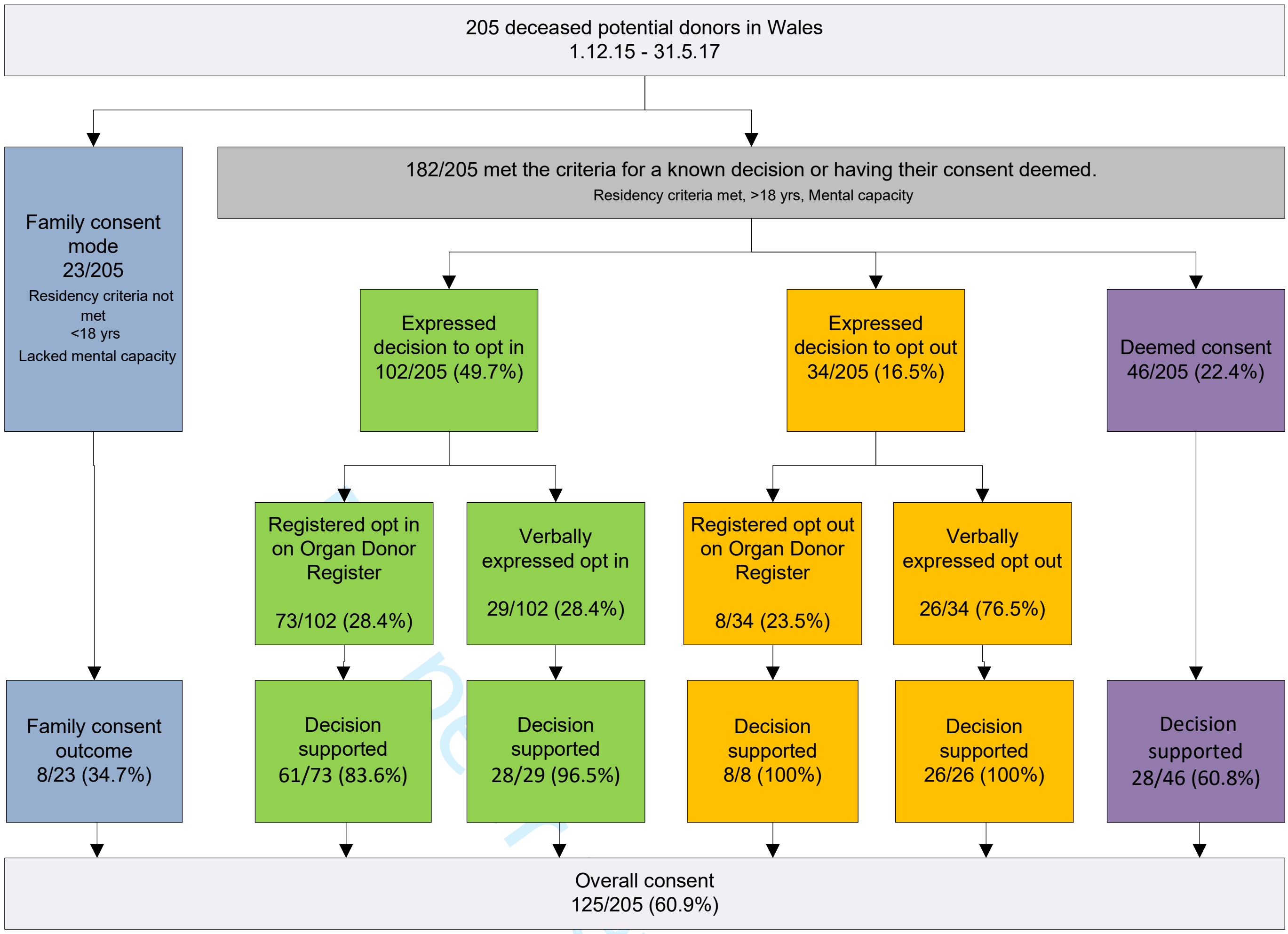
Patient and public representatives: Jeanette Bourne and CRUSE Bereavement Care Cymru, who provided leaflets signposting bereavement support for participants. Sarah Thomas Centre for Sight and Sound, Janet Thickpenny Big Lottery, Gethin Rhys Churches Together in Wales, Michael Rhys, Janet Williams and Gloria Owen.

Maria Mesa Women Connect First, Roon Adams Race Equality First, Michael and Jess Houlston Donor Family Network, Maria Battle Chair of Cardiff and Vale University Health Board, Anna Bates Believe, Llanelli Multicultural Network, Rita’s Café.

Bethan Moss Team Manager for reviewing the NHSBT anonymised database and supporting data analysis.
Lisa Welsh, team leader, Donor Records Department for ensuring packs, envelopes and consent forms were included in donor packs for the duration of the study. Keeping the research team updated and following up with postal follow ups.
Gill Drisma, Manager Donor Records Department (DRD), NHSBT for helping set up the data collection process and ensuring support staff were kept up to date of the study.
Lynne Woolcocks, Regional Office Manager, South Wales & South West Organ Donation and Transplantation for supporting the postal follow ups and co-ordinating with DRD to ensure all families had opportunity to participate in the study.

A special thank you to all the families. Thank you for agreeing to share your stories so that we could learn from your experiences.


205 deceased potential donors in Wales
1.12.15 - 31.5.17
Family consent mode
23/205
Residency criteria not met
<18 yrs
Lacked mental capacity
182/205 met the criteria for a known decision or having their consent deemed.
Residency criteria met, >18 yrs, Mental capacity
Expressed decision to opt in
102/205 (49.7%)
Expressed decision to opt out
34/205 (16.5%)
Deemed consent
46/205 (22.4%)
Registered opt in on Organ Donor Register
73/102 (28.4%)
Verbally expressed opt in
29/102 (28.4%)
Registered opt out on Organ Donor Register
8/34 (23.5%)
Verbally expressed opt out
26/34 (76.5%)
Family consent outcome
8/23 (34.7%)
Decision supported
61/73 (83.6%)
Decision supported
28/29 (96.5%)
Decision supported
8/8 (100%)
Decision supported
26/26 (100%)
Decision supported
28/46 (60.8%)
Overall consent
125/205 (60.9%)

BMJ Open

Short-term impact of introducing a soft opt-out organ donation system in Wales: Before and after study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025159.R2
Article Type:	Research
Date Submitted by the Author:	18-Feb-2019
Complete List of Authors:	Noyes, Jane; Bangor University, School of Social Sciences Mc Laughlin, Leah; School of Social Sciences Morgan, Karen ; Welsh Government, Major Health Conditions Policy Team Walton, Philip; NHS Blood and Transplant , Organ Donation Department, Unit 3 Cae Gwyrdd, Greenmeadow Springs Business Park, Tongwynlais, Cardiff, UK. Curtis, Rececca ; NHS Blood and Transplant Organ Donation and Transplantation Directorate, Statistics and Clinical Studies Madden, Susanna ; NHS Blood and Transplant Organ Donation and Transplantation Directorate, Statistics and Clinical Studies Roberts, Abigail; NHS Blood and Transplant Stephens, Michael; Cardiff and Vale University Health Board, University Hospital of Wales, Department of Nephrology and Transplantation, Heath Park, Cardiff, UK.
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health policy, Evidence based practice
Keywords:	HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

TITLE PAGE

Short-term impact of introducing a soft opt-out organ donation system in Wales: Before and after study.

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Abstract

Objectives
To determine the short-term impact of a soft opt-out organ donation system on consent rates and donor numbers.
Design. Before and after observational study using routinely collected data**.**
Setting: NHS Blood and Transplant.
Participants. 205 potential organ donor cases in Wales.
Interventions: The Act and implementation strategy.
Primary and secondary outcomes: Consent rates at 18 months post implementation compared with 3 previous years, and organ donor numbers 21 months before and after implementation. Changes in organ donor register activity post implementation for 18 months.
Results: The consent rate for all modes of consent was 61.0% (125/205), showing a recovery from the dip to 45.8% in 2014/15. 22.4% (46/205) were deemed consented donors: consent rate 60.8% (28/46). Compared with the 3 years before the switch there was a significant difference in Welsh consent rates (chi-squared p-value=0.009). Over the same time period, rest of the United Kingdom consent rates also significantly increased from 58.6% (5256/8969) to 63.1% (2913/4614) (chi-squared p-value < 0.0001), therefore the Wales increase cannot be attributed to the Welsh legislation change. Deceased donors did not increase:101 compared with 104. Organ donation registration increased from 34-38% with 6% registering to opt out.
Conclusion: The long-term impact on consent rates and donor numbers is unclear. Concerns about a potential backlash and mass opting out were not realised. The move to a soft opt-out system has not resulted in a step change in organ donation behaviour, but can be seen as the first step of a longer journey. Policymakers should not assume that soft opt-out systems by themselves simply need more time to have a meaningful effect. Ongoing interventions to further enhance implementation and the public's understanding of organ donation are needed to reach the 2020 target of 80% consent rates. Further longitudinal monitoring is required.

Strengths and weaknesses of the study

- Routinely collected data were analysed for all potential organ donor cases.
- A large group of patient and public representatives worked with researchers to co-produce the study.
- The study is limited to establishing short-term impacts and a longitudinal study with larger numbers is required to determine changes over time.

Original Protocol

Noyes J, Morgan K, Walton P, Roberts A, Mclaughlin L, Stephens M. Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: mixed-method study protocol. **BMJ Open.** 2017 Oct 12;7(10):e017287. doi: 10.1136/bmjopen-2017-017287

Funding statement

The study was funded by Health and Care Research Wales. Project Reference 1129.

Competing interest statement

There are no known competing interests.

Patient consent

Article contains no identifiable personal medical information.

Data sharing statement

Additional unpublished data are not publicly available.

INTRODUCTION

Around 6500 people are waiting for organ transplants in the United Kingdom (UK).[1] Organ transplantation is cost-effective and improves quality of life for recipients.[2] Organ donation consent rates in the UK need to improve to keep up with demand for transplants.[3]

Under the opt-in system in Wales, consent rates for deceased organ donation ranged between a high of 53.6% to a low of 48.5% between 2013-2015.[4] In contrast consent rates in some other European countries are much higher. For example, in Spain consent ranges from 80-85% in an opt-out system in which all citizens are automatically assumed to consent to organ donation unless they choose to state otherwise.[5]

The British Medical Association, patient groups and newspapers[6-7] have lobbied for the introduction of an opt-out system to replace the current opt-in system in the respective UK nations (England, Scotland, Wales, Northern Ireland). The UK nations have separate, and in the case of Scotland, Wales and Northern Ireland devolved, responsibilities for health. There are two types of 'opt-out' system: a 'hard' opt-out where the family are not consulted or a 'soft' opt-out where the family are consulted. Opinion is starkly divided as to the benefits of introducing either form of opt-out system of organ donation compared with reorganisation of the current opt-in system to increase consent rates.[8-9] A comparison of the opt-in and soft opt-out default systems can be found in Table 1. Box 1 contains key operational definitions.

Table 1. Comparison of the previous opt-in and new soft out-opt system in Wales.

	Decision Type			
	Active	Passive	Geographical reach	Role of family
Former Opt-in system	Expressed decision: Register to opt in on the organ donor register Verbally tell a relative or friend you want or do not want to be a donor Write telling a relative or friend you want or do not want to be a donor Nominate a representative to make the decision for you. (Nowhere to record this decision)	Do nothing and remain a non-donor	UK wide	To give consent for organ donation
New Opt-Out System in Wales	Expressed decision: Register to opt-in on the organ donor register Verbally tell a relative or friend you want to be a donor Write telling a relative or friend you want or do not want to be a donor Register to opt-out on the organ donor register Appoint a patient representative on the organ donor register to make the decision for you	Do nothing and remain as a donor (Deemed consent)	Wales only Welsh citizens have to die in Wales for the soft-opt out to apply. If they die in England the opt-in system applies.	To support the donation decision of their relative made in life

Box 1. Additional key terms and operational definitions

Key term	Definition
Opt-in organ donation system	The default is to be a non-donor unless an individual actively registers or expresses to be an organ donor.
Opt-out organ donation system	The default is presumed consent (called deemed consent in Wales) to organ donation, unless an individual actively opts out.
Hard opt-out organ donation system	The family are not consulted
Soft opt-out organ donation system	The family are consulted
Soft opt-out eligibility criteria Wales	Over 18 years, voluntarily resident in Wales, mental capacity, die in Wales.
Expressed decision	A person may register their decision on the organ donor register or convey it verbally or in writing to family members (see Table 1 for options available under the different systems).
Organ Donor Register	Under the former opt-in system individuals could only opt in to be a donor on the register. With the introduction of the soft opt-out system in Wales the register was amended so that individuals can opt in or opt out of organ donation on the register, and appoint a representative to convey the decision for them.
Presumed/Deemed consent	The terms are interchangeable, but in Wales the term used is deemed consent. A person* who has not actively expressed their organ donation decision during

	life is considered to have no objection to organ donation and their consent can be deemed. *Eligibility criteria apply.
Known donation decision	The potential organ donor has made their decision known during life time by either registering it on the organ donation register or conveying it verbally or in writing to family members/close friends.
Family consent in the soft opt-out system	Family consent is for children under 18 years, and for potential organ donors who do not meet residency criteria or lack mental capacity.
Organ donation decision overrides	Under the new soft-opt out system, family members are expected to support the organ donation decision of their relative made in life. To override their relative's decision family members should provide witnessed written evidence or a witnessed conversation that the potential organ donor had changed their mind and opted for a different donation decision (the last known decision).

Following an extensive public consultation, the Human Transplantation (Wales) Act 2013 introduced a soft opt-out system of organ donation, which was fully enacted on 1st December 2015.[10] The purpose of the Act is to make it easier for people to donate their organs to benefit patients. The primary aim is to increase consent rates. In the Welsh soft opt-out system unless the deceased person has expressed a decision in life (either for or against being be an organ donor) it will be assumed that they have no objection to organ donation and their consent can be deemed. Family members are expected to support the donation decision made by their relative in life.

How the intervention is intended to work

A detailed description of the components and how the intervention is intended to work can be found in the study protocol.[4] In summary, the Act, media campaign and implementation strategy were conceptualised as a complex behaviour change intervention. The Act changed the principles of consent to deceased organ donation from an opt-in to a soft opt-out system for adults 18 years or over; voluntarily resident for 12 months or more in Wales; who have not made an expressed decision regarding organ donation; and is competent to understand the notion of deemed consent. The individual must also die in Wales for the Act to apply. In addition to the public media campaign, there was an accompanying implementation strategy for National Health Service (NHS) and NHS Blood and Transplant (NHSBT) staff, which required amending clinical protocols and procedures and retraining large numbers of staff and all Specialist Nurses in Organ Donation (SNODs) covering Wales. The success of the Act depended on behaviour change of the public and professionals. The theory is that the neutral media campaigns supporting implementation will facilitate the behaviours in Welsh citizens outlined in Box 2.

Box 2. Intended behaviours of the citizens of Wales under the soft opt-out system.[4]

- opt-in or opt-out on the organ donor register (registered decision), with the option of appointing a patient representative
- discuss opt-in or opt-out donation decision with families and friends (express decision)
- do nothing and it will be assumed that the person does not object to organ donation (deemed consent)
- families will put aside their own views on donation and respect the decision of the deceased person made in life.

There are few examples where soft opt-out systems have been implemented in the context of rigorous research and no examples of process evaluations with family members who were approached about organ donation when a change to a soft opt-out system has been implemented. The aim of this study was to determine the short-term impact of the introduction of a soft opt-out system of organ donation on consent rates and organ donor numbers. Elsewhere we report the process evaluation findings of the nurse-led implementation of the soft opt-out system that help contextualise and explain the initial impacts.

METHODS

We worked with NHSBT to analyse a bespoke dataset of routinely collected data (including the Potential Donor Audit) on all potential organ donor cases, and organ donor registration activity for 18 months after the 1st December 2015 when the soft opt-out was implemented in Wales, compared with up to three years pre-implementation.[4] Welsh Government shared comparative figures on numbers of deceased donors for 21 months before and after implementation.[11] For the purposes of his study a potential organ donor was defined as a patient who is eligible for organ donation and whose family is approached for a formal organ donation discussion.

Primary and secondary outcomes: Consent rates and numbers of organ donors compared with previous years. Changes in organ donor register activity post implementation for 18 months.

Participants. All 205 potential organ donor cases in Wales were included.

Data collection and analysis

NHSBT routinely collected data on each case

Retrospective data on consent rates, donor numbers and transplant numbers are routinely collected for each financial year (12 months). We worked with NHSBT to analyse prospective data for 18 months post implementation on 1st December 2018. These data covered one full financial year and a period of months from two further financial years. NHSBT statisticians compiled summary reports of descriptive statistics for the 18 month post-implementation period and provided reports of comparative retrospective data, and statistical significance. A chi-squared test was used to determine whether there was a statistical difference in overall consent rates between the 3 years prior to the introduction of the soft opt-out and deemed consent compared to the 18-months following the introduction of the soft-optout and deemed consent (Table 2).[12] Rest of the UK national trends in consent rates were also used as a comparative context. Data were grouped by mode of consent (expressed and registered opt-in and opt-out; deemed, and family consent), and total numbers of families approached. Data on proceeding donors and transplants were also compared. In addition, Welsh Government shared their analysis of numbers of organ donors for 21 months pre and post implementation.

Ethics

The protocol was approved on 23/10/15 by NHSBT Research, Innovation and Technology Advisory Group (RINTAG). This approval included agreement to share anonymised NHSBT data. The study was approved by the Wales Research Ethics Committee 5 NHS research ethics committee (IRAS number 190066; Rec Reference 15/WA/0414 on 25/11/2015) and the NHSBT Research and Development Committee (NHSBT ID: AP-15-02 on 24/11/2015). Bangor University was the study sponsor.

Patient and Public Involvement

This was a co-productive study with extensive patient and public involvement of over 50 people and organisations in the design, analysis and interpretation of data. A 2-day residential meeting and an end of study event were convened to discuss and interpret findings. Patient and public involvement was most evident in the design and conduct of the associated process evaluation. A detailed report evaluating the impact of the co-productive approach and the contribution of patient and public representatives is published elsewhere.

RESULTS

There were 205 deceased donors in Wales of which 88.7% (182/205) met the criteria for a known decision (ie they expressed a decision in life (either for or against being be an organ donor) or having their consent deemed (Figure 1 and Table 2). The remaining 11.2% (23/205) cases met the criteria for the ‘family’ mode of consent as the deceased person was a child, lacked mental capacity or did not meet residency criteria. The consent rate for all modes of consent was 61.0% (125/205), showing a recovery from the dip to 45.8% in 2014/15. Compared to the consent rates in the 3 full financial years prior to the introduction of deemed consent in Wales there was a significant difference in the consent rates (chi-squared p-value=0.009). Over the same time period consent rates in the rest of the UK nations also significantly increased from 58.6% (5256/8969) to 63.1% (2913/4614) (chi-squared p-value < 0.0001), therefore whilst the observed increase in consent in Wales is positive, the increase cannot be attributed to the change in legislation in Wales.

When family consent was excluded, the consent rate for 182/205 cases that met the criteria for a known decision or deemed consent was 64.2%. Just over 22% (46/182) of cases were deemed consented donors with a consent rate 60.8% (28/46).

Seventy-nine percent (162/205) had registered or expressed a decision, of which 62.4% (128/205) of cases had registered or expressed their decision to opt-in. Fifty-seven percent (73/128) registered to opt-in on the organ donor register, and 22.6% (29/128) verbally expressed to opt-in with their families during their lifetime. Just over 16.5% (34/205) opted-out: 8/34 opted-out on the organ donor register and 26/34 expressed to their families that they wanted to opt-out.

Family members still overrode 15.1% (31/205) opt-in decisions to donate, including 16.4% (12/73) organ donor registered opt-in decisions; 3.4% (1/29) verbally expressed opt-in decisions, and 39.1% (18/46) deemed consents.

Of the 125/205 cases where consent to deceased donation was supported by family members, 69.6% (87/125) proceeded to donation. The number of deceased donors remained relatively static (101 compared with 104 21 months pre and post implementation).[11] The number of potential donors however fell over this period, so although the overall donor numbers stayed roughly the same, this was in the context of fewer potential donors. Finally, organ donation registration increased from 34-38%. As of June 2017, 1,181,709 people in Wales had opted-in and 176,011 opted-out, which is 6% of the population and less than the Government anticipated would opt-out.

Families approached by subsequent mode of consent: Deceased organ donation Wales	**Retrospective before**			**Prospective after implementation of the soft opt-out on 1st December 2015**			
	April 2012 – March 2013 12 months	**April 2013 – March 2014 12 months**	**April 2014-March 2015 12 months**	**Dec 2015- Mar 2015 4 months**	**April 2016 – March 2017 12 months**	**April 2017 May 2017 2 months**	**Total Dec 2015- May 2017 18 months**
Total families approached: number of cases	**161**	**169**	**153**	**54**	**141**	**10**	**205**
Total cases that met the criteria for a known decision or having their consent deemed. Excludes family consent (child, not Welsh resident, lacks mental capacity)	**N/A**	**N/A**	**N/A**	**51/54 (94.4%)**	**124/141 (87.9%)**	**7/10 (70.0%)**	**182/205 (88.8%)**
Expressed consent:	56/161 (34.8%) Registered opt in on ODR 48/56 (85.7%) Verbally expressed opt in 7/56 (12.5%) Other 1/56 (1.8%)	62/169 (36.7%) Registered opt in on ODR 52/62 (83.9%) Verbally expressed opt in 10/56 (17.8%)	48/153 (31.4%) Registered opt in on ODR 43/48 (89.6%) Verbally expressed opt in 5/48 (10.4%)	21/51 (41.2%)	76/124 (61.3%)	5/7 (71.4%)	**102/205 (49.7%) Registered opt in on ODR 73/102 (71.6%) Verbally expressed opt in 29/102 (28.4%)**
Deemed consent	N/A	N/A	N/A	13/51 (25.5%)	31/124 (25.0%)	2/7 (28.6%)	**46/205 (22.4%)**
Family consent	105/161 (65.2%)	107/169 (63.3%)	105/153 (68.6%)	3/51 (5.9%)	17/124 (13.7%)	3/10 (30.0%)	**23/205 (11.2%)**
Total patient opt-outs:	**N/A**	**N/A**	**N/A**	**17/51 (33.3%)**	**17/124 (13.7%)**	**0**	**34/205 (16.5%)**
Registered opt out on ODR	N/A	N/A	N/A	3/17 (17.6%)	5/124 (4.03%)	0	**8/34 (23.5%)**
Verbally expressed opt out	N/A	N/A	N/A	14/17 (82.3%)	12/124 (9.7%)	0	**26/34 (76.5%)**
Mode of consent ascertained (consent rate)							
Total consent ascertained*	**81/161 (50.3%)**	**91/169 (53.8%)**	**70/153 (45.8%)**	**29/54 (53.7%)**	**90/141(63.8%)**	**6/10 (60.0%)**	**125/205 (61.0%)**
Total consent for cases that met the criteria for a known decision or having their consent deemed.	**N/A**	**N/A**	**N/A**	**27/51 (52.9%)**	**85/124 (68.5%)**	**5/7 (71.4%)**	**117/182 (64.2%)**
Expressed consent	48/56 (85.7%)	53/62 (85.5%)	37/48 (77.1%)	18/21 (85.7%)	66/76 (86.8%)	5/5 (100%)	**89/102 (87.2%)**
Deemed consent	N/A	N/A	N/A	9/13 (69.2%)	19/31 (61.2%))	0	**28/46 (60.8%)**
Family consent	33/105 (31.4%)	38/107 (35.5%)	33/105 (31.4%)	2/3 (66.6%)	5/ 17 (29.4%)	1/3 (33.3%)	**8/23 (34.7%)**
Overrides by family members							
Total overrides by family members	**8/161 (5%)**	**9/169 (5.3%)**	**11/153 (7.2%)**	**7/54 (12.9%)**	**22/141 (29.1%)**	**2/10 (20%)**	**31/205 (15.1%)**
ODR overrides	8/48 (16.7%)	7/52 (13.5%)	10/43 (23.3%)				**12/73 (16.4%)**
Other expressed overrides	0	2/10 (20%)	1/5 (20%)				**1/29 (3.4%)**

Deemed consent	N/A	N/A	N/A				**18/46 (39.1%)**
Proceeding donors by mode of consent							
Expressed consent: Verbal or ODR registration	26/48 (51.4%)	33/53 (62.2%)	28/37 (75.7%)	13/18 (72.2%)	43/66 (65.1%)	4/5 (80.0%)	**60/89 (67.4%)**
Deemed consent	N/A	N/A	N/A	9/9 (100%)	11/19 (57.9%)	0	**20/28 (71.4%)**
Family consent	24/33 (72.3%)	21/38 (55.3%)	26/33 (78.8%)	2/2 (100%)	4/5 (80.0%)	1/1 (100%)	**7/8 (87.5%)**
Total	**52/81 (64.2%)**	**54/91 (59.3%)**	**60/70 (85.7%)**	**24/29 (82.7%)**	**58/90 (64.4%)**	**5/6 (83.3%)**	**87/125 (69.6%)**
Organs donated by mode of consent							
Expressed consent: Verbal or ODR registration	89	108	100	44	136	17	**197**
Deemed consent	N/A	N/A	N/A	31	39	0	**70**
Family consent	88	69	78	12	10	4	**26**
Total	**177**	**177**	**178**	**87**	**185**	**21**	**293**
Organs transplanted by mode of consent							
Expressed consent: Verbal or ODR registration	83	97	87	36	116	15	**167**
Deemed consent	N/A	N/A	N/A	26	33	0	**59**
Family consent	82	63	62	12	9	2	**23**
Total	**165**	**160**	**149**	**74**	**158**	**17**	**249**
Comparative total consent ascertained rate for England	57.9%	59.6%	58.5%		62.5%		
Comparative donor numbers* Figures shared by Welsh Government for 21 months pre and post[8] *Before and after change in consent rates not statistically significant when rest of the UK increases in organ donation consent rates over the same time period are factored in.	21 months pre - 101			21 months post- 104			

Table 2. Before and after results.

DISCUSSION

Whilst the observed increase in consent rates in Wales is positive, it is too early to tell if the soft-opt out system will be successful in further increasing consent rates compared with the rest of the UK nations. It is clear from the analysis that the move to a soft opt-out system has not resulted in a step change in organ donation behaviour, but is the first step of a longer journey.

Although there was general support for the soft opt-out system, decisions made by the citizens of Wales during life were not consistently supported as intended by family members in death. The success of the soft opt-out system is dependent on family members supporting their relative's donation decision made in life. Consent rates would have been higher if family members had consistently supported their relative's opt-in decision, although this would apply to both opt-in and opt-out systems. Whilst acknowledging that numbers are too small at this stage to undertake a more sophisticated statistical analysis, and the introduction of new modes of consent (with new potential opportunity to override) make direct comparisons difficult to interpret, there was an observed upward trend in family overrides following introduction of the soft-opt out system (Table 2). For the three years prior to implementation family overrides ranged from 5-7.2%. Post implementation it was 15.1% over 18 months, and 29.1% in 2016/17. Some of the increase can be explained by the introduction of deemed consent, which provided a new opportunity to override that did not exist before. The reasons why family members still override their relative's opt in decision are numerous and complex and our process evaluation published elsewhere provides a detailed explanation to contextualise the findings reported here. Importantly, process evaluation findings show that SNODs were not able to establish the required standard of evidence to override an opt in donation decision made in life. They accepted a lesser standard of evidence and donation did not proceed.

Assuming that the potential donor had not changed their decision from opt-in to opt-out, it appears that some family members were not able to put their own negative views on organ donation aside. Similarly, Shaw describes scenarios whereby family members objected to organ donation and deemed consent specifically.[13] We found that family members have yet to accept 'doing nothing' (deemed consent) as a positive decision in support of organ donation. The fact that the consent rate obtained via deemed consent is the same as the overall consent rate is an important and reassuring finding. There was some support for Shaw's assumption that families are more likely to overrule a consent that is merely presumed (the equivalent of deemed consent in Wales) in that post implementation family support for an expressed decision made in life (87.2% 89/102) was higher than for a deemed decision (60.8% 28/46).[14] Nonetheless, post implementation, overall consent rates were brought down by the low rate of family consent for children, and potential donors who did not have mental capacity or meet residency criteria (34.7% 8/23).

The Act contains provision whereby a person can appoint a representative on the organ donor register to convey their donation decision when they die. Only 33 people had appointed a representative during the timeframe of the study (now risen to 35) and none were called upon during the first 18 months. If people are concerned that their relatives may not honour their donation decision, then appointing a representative may mitigate this relatively common situation. There is no appetite in Wales to introduce a hard opt-out system that removes the family from the decision-making process. Family members may however benefit from additional education to further clarify that it is not their decision to make and that their role is to support the donation decision made in life by their relative. The rate of family overrides needs monitoring in the long-term to determine if the observed upward trend is a cause for concern that requires further investigation.

At an individual potential donor level it has been made easier to convey a decision to donate organs. Sixty percent of cases were either registered on the organ donor register or had discussed their donation decision with family member(s), and as of March 2018, 39% of the population are registered to opt in to donate on the organ donor register. Any fears that introducing an opt-out system would cause a backlash by somehow changing the concept of the 'gift' of organ donation has not been realised. Only a relatively small number of people have thus far opted out (6%) on the organ donor register, and people are still opting in more than previously.

A more complex analysis was not performed given the small numbers involved in the first 18 months following introduction of the soft opt-out system and deemed consent in Wales. Small numbers, year on year fluctuations in potential deceased donors and consent rates, and health systems issues help explain why it has been difficult historically to establish if an opt-out system is the right option to introduce, and why increased consent rates have not yet translated into increased donor numbers. In Spain, it took 10 years following introduction of a soft opt-out system and further reorganisation to achieve 80% consent rates and increased donor numbers.[4-6] As a trial was not feasible, it was not possible to determine with certainty if the 60.8% (28/46) of families who supported deemed consent under the soft opt-out system would have given their consent anyway under the former opt-in system. Nor do we know for sure why overall consent rates dropped by 5% to 48.5% immediately prior to implementation of the Act. Nonetheless, since its introduction there has been a sustained recovery and a 12.5% improvement since 2013/14. One explanation is that there was a high profile coroner's case in Wales in December 2014, which received international attention.[15] Donor numbers across the UK fell following the news coverage (the only year on year fall in donor numbers in the UK in the last decade). One additional hypothesis is that introducing a soft opt-out system created harm that caused the pre-implementation drop. McCartney writing in the BMJ[9] suggested that '*some or many of those opting out may have been willing to donate freely but not under uncertain legislation'*. This was a view supported by patient and public representatives who co-produced the current study. In a separate analysis of media coverage,[16] we found a change to a more positive and supportive tone after 1st December 2015 when the soft opt-out was fully implemented that aligns with a general trend in improvements to consent rates.

Discounted over ten years, the costs were approximately £7.5 million to set up and maintain the infrastructure required to operate a soft opt-out system of organ donation, including business and system changes, the processing of opt-out requests, public communications, and evaluation. An increase of one donor per year with associated increases in organ transplantations, would generate sufficient benefits for a soft opt-out system to more than pay for itself.[17] With this in mind, further attention needs to be given to reducing the number of consented donors who do not proceed to donation. During the 18 months post implementation around 30% of consented donors did not proceed. Our process evaluation sheds more light on the issues that prevent donation proceeding, some of which are amenable to intervention to reduce this figure.

Our findings have important implications for other nations including the Netherlands, Scotland and England who have signalled an intention or decision to implement a soft opt-out system.[18-21] Our process evaluation makes clear that there are many different issues that impact on whether or not a family supports their relative's organ donation decision, which could be addressed. A longitudinal study is required to see if consent rates are maintained, continue to improve, and subsequently reach the national UK target of 80% by 2020,[22] and to monitor what happens to donor numbers. Having accumulated more data since the conclusion of this study, other NHSBT studies are underway which are looking into this. We also need to know and understand the specific reasons why 6% of people have opted out on the organ donor register.

CONCLUSION

We found that introduction of the soft opt-out reversed a decline and subsequently improved consent rates for deceased organ donation in Wales that were similar to other improvements in consent rates in the rest of the UK nations who had not implemented a soft-opt out system; and had no impact on donor numbers. Whilst the soft opt-out system in Wales has been most successful in getting potential organ donors to register or verbally express their decision, or do nothing and have their consent deemed, it was primarily family member overrides and health systems issues that prevented support for their relative's opt-in donation decision and successful donation.

Given the growing worldwide interest in introducing opt-out systems and the unclear long-term impact on consent and donation rates these findings should be considered by policymakers who may assume that soft opt-out systems by themselves simply need more time to have a meaningful effect on donation numbers.

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List of Figures

Author contributions

Jane Noyes – Chief Investigator conceptualised the idea, put the team together, designed the study and procedures, and drafted manuscript.

Michael Stephens - Consultant Transplant and Organ Retrieval Surgeon, Clinical Lead for Transplantation, Cardiff and Vale Health Board - advised on key research team members and stakeholders to bring into the research team, proposed changes in the law and key research questions to address.

Karen Morgan – Formerly Regional Manager South Wales and South West, NHSBT and now Major Health Conditions Policy Team, Directorate of Health Policy, Health and Social Services Group, Welsh Government – advised on key changes to policy and practice, study design and processes, data collection tools and implementation of the study.

Philip Walton – Regional Manager South Wales NHSBT advised on on changes to policy and practice, study design and processes, data collection tools, and implementation and analysis of the study.

Abigail Roberts – Specialist Nurse in Organ Donaiton NHSBT advised on the role of the Specialist Nurse in Organ Donation, study design and processes, data collection tools and implementation and analysis of the study.

Leah Mclaughlin – Research Officer – finalised study procedures and data collection processes, designed the study documentation and logos and supported production of applications to the NHS REC and NHSBT R&D committees, undertook fieldwork and analysed data.

Susanna Madden and Rebecca Curtis – Statisticians at NHSBT - undertook the statistical analysis.

All authors contributed to drafting and agreed the final submitted manuscript.

Acknowledgments

Fiona Wellington: Head of Operations NHSBT for supporting the study. Christian Brailsford: NHSBT provided advice and support to agree a mutual data sharing agreement and negotiate NHS ethics and NHSBT RINTAG and NHSBT R&D processes. Pat Vernon (Policy Lead Welsh Government), Ian Jones (Research and Evaluation Lead), Caroline Lewis (Organ Donation Policy Manager) provided a Government perspective and shared research carried out prior to implementation of the Act.

Donald Fraser: Lead of the Wales Kidney Research Unit supported development of the funding application and served as independent Chair of the steering group.

Carol Williams for undertaking Welsh language and some English interviews. Jo Mitchell for providing administrative support and transcription. Barbara Neukirchinger (intern), Natalie Roberts (intern).

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Patient and public representatives: Jeanette Bourne and CRUSE Bereavement Care Cymru, who provided leaflets signposting bereavement support for participants. Sarah Thomas Centre for Sight and Sound, Janet Thickpenny Big Lottery, Gethin Rhys Churches Together in Wales, Michael Rhys, Janet Williams and Gloria Owen.

Maria Mesa Women Connect First, Roon Adams Race Equality First, Michael and Jess Houlston Donor Family Network, Maria Battle Chair of Cardiff and Vale University Health Board, Anna Bates Believe, Llanelli Multicultural Network, Rita’s Café.

Bethan Moss Team Manager for reviewing the NHSBT anonymised database and supporting data analysis.
Lisa Welsh, team leader, Donor Records Department for ensuring packs, envelopes and consent forms were included in donor packs for the duration of the study. Keeping the research team updated and following up with postal follow ups.
Gill Drisma, Manager Donor Records Department (DRD), NHSBT for helping set up the data collection process and ensuring support staff were kept up to date of the study.
Lynne Woolcocks, Regional Office Manager, South Wales & South West Organ Donation and Transplantation for supporting the postal follow ups and co-ordinating with DRD to ensure all families had opportunity to participate in the study.

A special thank you to all the families. Thank you for agreeing to share your stories so that we could learn from your experiences.

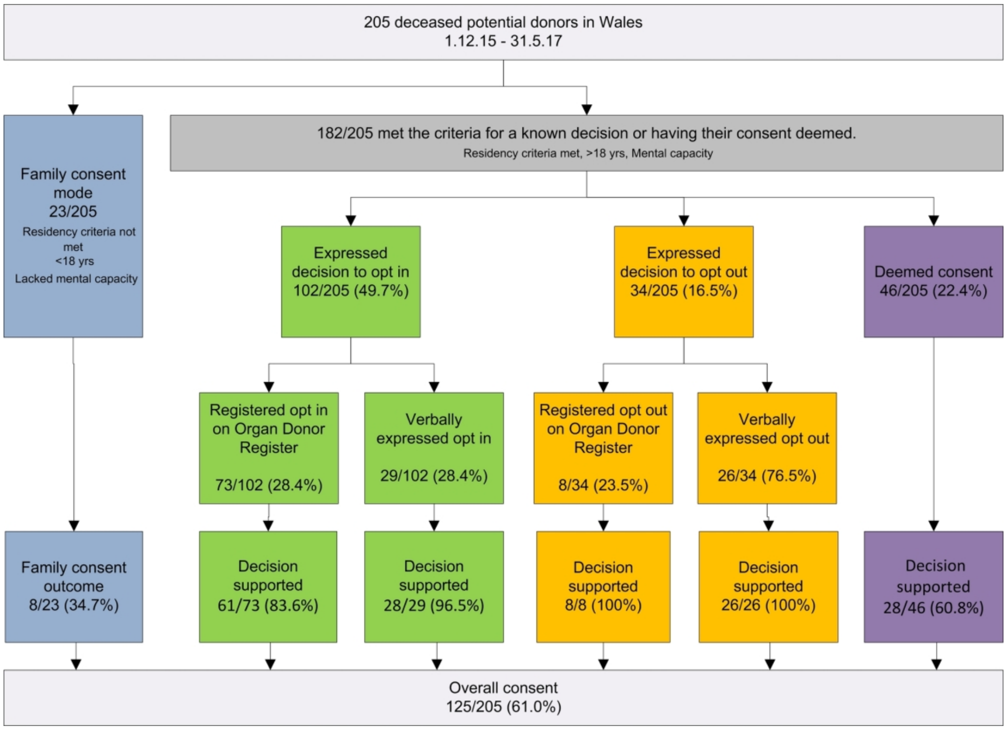

Figure 1. Consent outcomes.

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