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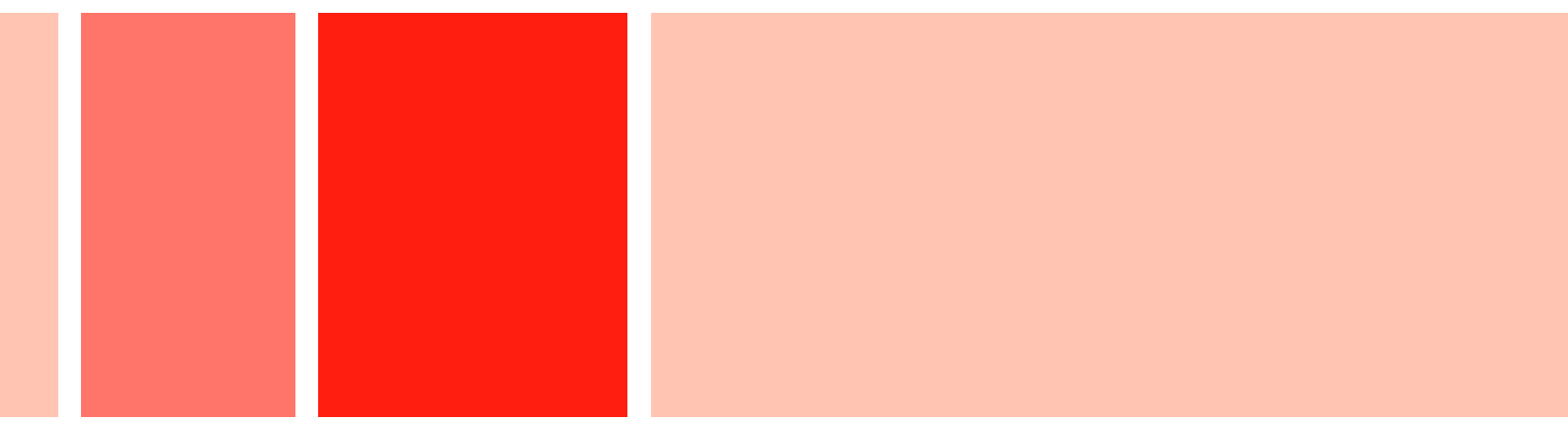
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Impact evaluation of the Human Transplantation (Wales) Act: Analysis Plan



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Table of contents

1. Background and objectives	2
2. Rationale for the impact evaluation	4
3. Existing evaluation strands	5
4. Analysis plan	6
4.1 Routine data from NHSBT	7
4.2 Research with the general public and NHS staff	8
4.3 Assessing the outputs from the existing evaluation strands	9
5. Timetable – key milestones	10
Annex 1 - Main variables of interest	11

List of tables and figures

Tables

Table 1	Existing evaluation strands	4
Table 2	Timetable	9
Table 3	Main variables of interest	10

Figure

Figure 1	Deceased organ donation rates	7
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1. Background and objectives

Organ transplantation has become one of the most successful medical procedures as just one person can save or improve up to nine lives by donating their organs, and more still by donating their tissues. Polls have shown that the majority of the population across the UK are in favour of organ donation, but the number of people putting themselves on the Organ Donor Register does not reflect this widespread support. Another problem is that very few people die in circumstances under which they can become eligible donors¹ and therefore it is vitally important to maximise the chances of finding suitable donors by encouraging as many people as possible to express a decision, by joining the Register or making their decision clear to family and friends.

Under the current Human Tissue Act 2004 for England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act 2006, for organs to be available for transplantation, the individual concerned must consent to their use on an 'opt-in' basis. The Acts presume that a person does not want to donate their organs unless they have expressly indicated a decision to do so, for example by signing the Organ Donor Register or carrying a donor card.

Once opt-in consent is established, relatives are encouraged to support the deceased's decision. If no record exists of the deceased's decision, their family or another qualifying individual is able to agree to or refuse donation.

In order to increase the number of organs available for transplant, the Welsh Government took the decision to change the current organ donation system. The National Assembly for Wales passed the Human Transplantation (Wales) Act 2013 which sets out how consent is to be given for deceased organ and tissue donation in Wales. This law will come fully into force on 1 December 2015, following a two year communications campaign to raise awareness of the law. Until then, the current opt-in system remains in place in Wales, as in the rest of the UK.

The main aim of the 2013 Act is to increase the number of organs available for transplantation by changing how consent to donation is given. It states that donation is lawful in Wales when either express or deemed consent has been given. It will introduce a 'soft opt-out' system, in contrast to the opt-in system which is currently operational across the UK. Under this system, three choices will be available, allowing people to:

1. Opt in – register a wish to be a donor; or
2. Opt out – register a wish NOT to be a donor; or
3. Do nothing – in which case the person will be regarded as having no objection to organ donation – this is called 'deemed consent'.

¹ Only around one per cent of people in the UK die in circumstances under which they can become donors, according to NHSBT. This is based on there being 5,490 eligible donors out of approximately 570,000 deaths in the UK in 2013-14 (NHSBT Transplant Activity Report 2013-14).

The change to the organ donation consent system is substantial and as such, it is essential for members of the public to fully understand what the changes mean, and the choices they can make. The Welsh Government is therefore undertaking a long-term advertising campaign to raise awareness of the change to the organ donation system and the choices people will have.

Based on a systematic review of international evidence², the Welsh Government believes that switching to an opt-out system will lead to an increase in the number of organs available for transplantation. A clear majority of the Welsh public supports the change³, despite a relatively low proportion actually being on the Organ Donor Register (33 per cent in Wales, in line with the rest of the UK).

Under an 'opt-out' or 'deemed/presumed consent' system, every person living in Wales (aged 18 or over – the law will not apply to children) who has the required mental capacity is deemed to have given their consent to organ donation, unless they have taken the deliberate step of opting out.

An international systematic review conducted by the University of York in 2008 (Rithalia et al., 2008)⁴ which examined the impact of opt-out or presumed consent legislation on organ donation rates and the Welsh Government review both suggest that an association exists between presumed consent legislation and increased organ donation rate. For example, Bilgel (2012)⁵ included data from 24 countries over the period 1993-2006 and estimated that countries with presumed consent legislation have on average 13-18 per cent higher organ donation rates than countries with informed consent legislation.

In addition there is some evidence to suggest that people who live in a 'presumed consent' country were more likely to be willing to donate not only their own organs but a relative's organs. This was cited in Mossialos et al (2008)⁶ analysis of individual-level survey data from 15 European countries. They found that individuals living in presumed consent countries were between 17 and 29 per cent more likely to report willingness to donate their own organs and 27-56 per cent more likely to report that they would be willing to consent to the donation of their relatives' organs compared to respondents living in explicit consent countries.

The proposed system in Wales will be a 'soft' as opposed to a 'hard' opt-out system. In a hard opt-out system, families would not be consulted about organ

² Available here: <http://gov.wales/statistics-and-research/opt-out-systems-of-organ-donation/?lang=en>

³ In November 2014, 64 per cent of adults in Wales were in favour of changing to an opt-out system, while 17 per cent were against (<http://gov.wales/statistics-and-research/public-attitudes-organ-donation/?lang=en>)

⁴ Rithalia et al (2008). *The potential impact of an opt out system for organ donation in the UK*. Department of Health: London.

⁵ Bilgel (2012). 'The impact of presumed consent laws and institutions on deceased organ donation'. *European Journal of Health Economics* 13(1): 29-38.

⁶ Mossialos et al (2008). 'Does organ donation legislation affect individuals' willingness to donate their own or their relative's organs? Evidence from European Union survey data'. *BMC Health Services Research* 8:48.

donation if consent was either expressly given or presumed. In a soft opt-out system, families are involved in discussions about organ donation both to provide information about the person's residency, social and medical history and to be able to say if they knew the deceased person objected to donation.

The key difference for families compared to the current system is that, in the absence of a recorded decision, they will know their relative could have opted out but chose not to do so. This is thought likely to be the trigger for more donations to go ahead.

The change to the organ donation system is part of the Welsh Government's commitment to the UK-wide strategy *Taking Organ Transplantation to 2020*⁷ – a collaborative strategy between NHSBT and the health administrations of the four UK countries which sets out targets for improving donation rates.

2. Rationale for the impact evaluation

The Explanatory Memorandum that accompanied the Human Transplantation (Wales) Bill outlines the Welsh Government's commitment to monitoring and evaluating the impact of the legislation, stating:

“Owing to the lack of precision regarding changes in organ donation numbers that may occur as a result of introducing an opt-out system, it is imperative that the impact of the proposed legislation is monitored and evaluated. It will be particularly useful to compare changes in organ donations in Wales with England as the opt-in system will be retained in England for the foreseeable future.”

Human Transplantation (Wales) Bill: Explanatory Memorandum (2012, p.38)

The impact of the Act can be demonstrated by any change in deceased donor numbers after 1st December 2015 (and perhaps prior to this date as knowledge builds of the changes being introduced). However, the time period available is relatively short – no more than six full quarters of data can be used for the impact evaluation – and the numbers involved for Wales are still likely to be quite small and therefore subject to a degree of volatility (see Figure 1 for trends over time).

The evaluation will also need to compare the donor trends in Wales with those across the rest of the UK where different efforts are being made to increase the level of organ donation. While the data collated by NHS Blood and Transplant (NHSBT) will be central to the evaluation, impact will also be measured by examining trends in wider attitudes in Wales, using results from the regular surveys of the adult population as well from research among NHS staff.

⁷ Available here: <http://www.nhsbt.nhs.uk/to2020/>

3. Existing evaluation strands

In order to evaluate the implementation and impact of the Act, a number of research projects have been commissioned by the Welsh Government. A baseline survey has taken place with NHS staff to allow for comparisons of levels of awareness and knowledge over time and several waves of the public attitude survey have now been completed. Further details are provided in the table below.

Table 1: Existing evaluation strands	
Evaluation strand	Dates
<i>Survey of public attitudes in Wales to organ donation</i>	Baseline survey published in June 2012. Repeated at regular intervals up to June 2016.
<i>Exploring the views of the Welsh public (qualitative research)</i>	Baseline published in 2014 Second stage planned for after the implementation of the Act
<i>Researching the views of Specialist Nurses (SNODs) and Clinical Leads for organ donation (CLODs) in Wales (qualitative)</i>	First stage published August 2013. Further stages planned for the run up to, and following, the implementation of the Act.
<i>Measuring wider NHS staff attitudes in Wales</i>	Baseline survey published in Summer 2014. Second phase to take place in 2016.

Each of these individual evaluation activities has its own reporting process but the Welsh Government has commissioned an overall impact evaluation to draw together the evidence from the four strands shown above and to conduct an analysis of routine transplantation data from NHSBT (for the whole of the UK).

The overall aim of this evaluation is to assess the implementation of the Act and the impact it has on organ donation rates in Wales. There are specific objectives in relation to the individual strands of the process:

- Use routine data to monitor changes in organ donation and consent rates over time (outcome measures);
- Assess the effectiveness and impact of the communications campaign on public attitudes to, and understanding of, a soft opt-out system of organ donation;
- Understand current behaviour of individuals in relation to organ donation, and the impact that moving to a soft opt-out system will have (including whether or not individuals discuss wishes with family);
- Assess the implementation and impact that the legislation has on the work of Specialist Nurses and Clinical Leads, including feedback on training, and issues regarding family consent; and
- Monitor the awareness and attitudes of NHS staff involved in the referral process about the new law, its implementation and impact.

All of this evidence will be synthesised and summarised in a final overall report that will be published in late 2017. The report will also include suggestions for further research and for how the on-going impact of the Act might be evaluated over the longer term.

Central to the impact evaluation is the Analysis Plan laid out in this document. It is being published to transparently map out the data that will be used and analysis techniques being employed for assessing the initial impact of the Act, in the context of Wales having a different consent system to the rest of the UK. If there are material changes during the course of the evaluation, a new version of the plan will be made public.

4. Analysis plan

This section sets out the initial analysis plan for measuring the impact of the Act. The main variables of interest at this stage of the evaluation are listed in Annex 1.

Given the diverse existing evaluation strands and the over-riding difficulty of attributing any changes in donation rates to the impact of the Act, the evaluation will consider a number of approaches to analysis. One option is to follow the precepts of contribution analysis, an approach for inferring probable causality in real-life programme evaluations.

Contribution analysis has been described as:

“[...] an approach designed to reduce uncertainty about the contribution the intervention is making to the observed results, through an increased understanding of why the observed results have [or have not] occurred [...] and the roles played by the intervention and other internal and external factors.”

Better Evaluation⁸

This analysis will attempt to assess the relative importance of any movement in public attitudes to opting out (rather than opting in) and of any changes in the attitudes and practices of medical and nursing staff to any shift in outcomes (i.e. levels of organ donation). This analysis will be informed by the coefficients in the statistical analysis of the changes and trends within the Welsh donor data and through the comparison of trends in both the UK and Welsh data.

Another approach could be to develop a single analytical framework that would list the key evaluation questions (for example, does the programme increase donation levels?) and then populate the framework with data from the different evaluation strands. The framework would then be analysed to identify where there is stronger or weaker evidence to corroborate impact on, for example, changes in donation levels. Where the data point to the same or similar results, we can infer compelling associations but not causality.

⁸ Available here: http://betterevaluation.org/plan/approach/contribution_analysis

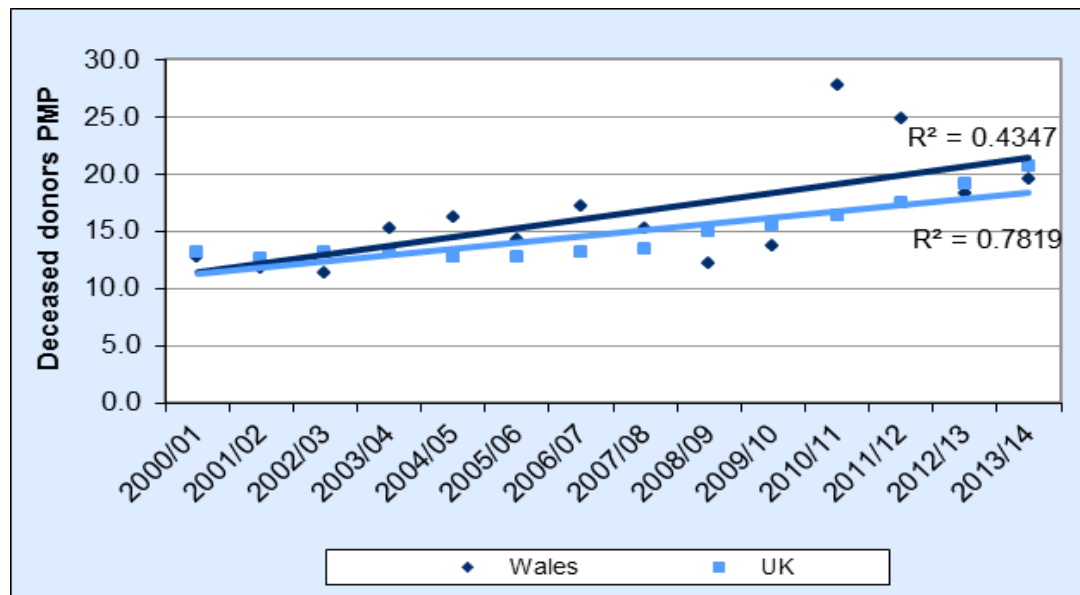
The following sub-sections of the analysis will be discussed in turn:

- Analysis of routine NHSBT data
- Collateral data on public attitudes from regular surveys in Wales
- Synthesising evidence from the other strands of the evaluation

4.1 Routine data from NHS Blood and Transplant

Figure 1 (below) shows the trend in organ donation over the period leading up to the start of the evaluation process in Wales. There is some evidence to suggest that deceased donation rates were growing faster in Wales between 2010 and 2012 but over the period shown there is little difference between the Welsh data and that for the UK as a whole. The most recent figures, for 2013/14, show 19.5 deceased donors per million people (PMP), compared with 20.6 for the entire UK. The evaluation will continue to monitor the trends in Wales and compare them with patterns in the rest of the UK and also with individual nations or regions with broadly similar demographic profiles.

Figure 1: Deceased organ donation rates 2000/01 to 2013/14



Data source: NHSBT

Figures include donors after circulatory death (DCD) and donors after brain death (DBD).
Living donors not included

As the anonymised data from NHSBT is available for the whole of the UK, the impact evaluation will employ a form of propensity score matching by developing an estimation equation using all non-Welsh data for the two main diagnostic codes – donation after brain death (DBD) and donation after circulatory death (DCD) as dependent variables, and then apply that equation to the corresponding characteristics of the Welsh population. Depending on the characteristics and distribution of that data, this may be based on simple multivariate (logistic) regression or may involve random effects multi-level modelling, for example where several years of data are being considered.

It may be appropriate to carry out separate analyses for the last 5+ years in that the response characteristics of different socio-demographic groups may have changed differentially in Wales as compared to the rest of the UK. With regular updates from NHSBT, the evaluation will have access to up to six full quarters of routine data after the Act comes into force so the two techniques of difference-in-difference and regression discontinuity analysis will now be more powerful. The analysis will also be assessing whether there are any signs of changes in trends of donation in the lead-up to the new consent system.

4.2 Research with the general public and NHS staff

Collateral Data: For Wales, there have been (and will be) collateral evidence from the following:

- Multiple waves of the public attitudes survey
- Exploring the detailed views of the public via qualitative research
- Researching the views of Specialist Nurses and Clinical Leads
- Measuring wider NHS staff attitudes

It is not within the scope of this evaluation to reproduce these outputs across the rest of the UK, although we will make use of any other published data that will inform the evaluation. However, to provide at least some counterfactual evidence on public attitudes, we will use the GfK NOP Random Location Omnibus (with about 1,800 interviews from Scotland, England and Northern Ireland) to include a short set of questions corresponding to key items in the Public Attitudes Survey (to be chosen after examining the results and any emerging trends) which would provide some marker corresponding data for the rest of the UK. Possible examples of UK-wide questioning include measures of:

- Attitudes to an opt-out system being introduced in the rest of the UK (in favour/against/need more information to decide)
- Predicted behaviour under an opt-out system (opt-out/opt-in/do nothing)
- Whether respondents have discussed their organ donation wishes with their family

Given the similar data collection methods for the Public Attitudes Survey in Wales and the Random Location Omnibus in the rest of the UK (face-to-face, in-home), we are on firm ground in terms of using this to provide better context for the findings. The UK data will be collected at the same time as the final wave of the Welsh fieldwork with the general public (currently planned for June 2016).

4.3 Assessing the outputs from the existing evaluation strands

As noted, there are four strands of evaluation evidence already commissioned by the Welsh Government and the findings from these activities will be distilled into the overall report for the impact evaluation. To some extent, this process is going to repeat and summarise some of the content of the original standalone outputs but the overall evaluation will be looking to link findings across the various strands in terms of themes or hypotheses. For example, it is expected that the qualitative research evidence (notably with CLODS and SNODs) will shed light on practical changes, including conversations with families.

We would seek to carry out further analysis of the survey data, especially of the general public surveys as this is a large source of evidence and is crucial to the successful implementation of the Act.

There are already some early indications of trends in the general public survey data, such as the rise in awareness of the change in the law. However, many of the shifts in opinion seem to have occurred between 2012 and 2013, rather than during 2014 and we are aware that there could be periods of flat-lining during the tracking stages of this part of the evaluation.

The public attitudes data should present some opportunities for secondary statistical analysis and more detailed profiling through merging data from waves where there is flat-lining in order to boost the sample size for analysis. Depending on the emerging question sets, there could also be the possibility of using segmentation techniques to profile different groups in population (for example, from hard-core opponents through cautious supporters to enthusiasts). If the emerging evaluation analyses suggest new areas of questioning, the impact evaluation might also recommend amending the coverage of the tracking data, perhaps by adding new material to a scheduled wave of the general public survey.

The two waves of surveys with NHS staff in Wales would also feed into the evaluation reporting. One phase has been completed and the questionnaire content for the second wave will inform the overall evaluation as well as this individual strand.

The evaluation intends to provide the most robust practical measurement of the impact of the Act but we are conscious of the potential difficulties in doing so⁹, such as the opt-out being introduced in Wales during a period of steady improvement in UK-wide donation rates following the recommendations of the 2008 organ donation taskforce and the continuing influence of family members over the donation process. There are also likely to be a range of lower profile interventions in other parts of the UK that might impact on donation rates in, for example, parts of England.

⁹ For example, see Douglas, J.F. and Cronin, A.J. (2015) 'The Human Transplantation (Wales) Act 2013: an Act of Encouragement, not Enforcement', *The Modern Law Review*, 78(2), 324-348. Available here: <http://onlinelibrary.wiley.com/doi/10.1111/1468-2230.12117/abstract>

5. Timetable

Table 2 (below) shows the key milestones for data collection, analysis and publication for the impact evaluation.

Table 2: Timetable	
Milestones	Dates
Publication of Analysis Plan	June 2015
On-going surveys among the general public	Through to summer 2016
Final phases of qualitative research and survey of NHS staff	Spring 2016
Final wave of the quarterly general public survey in Wales	June 2016
UK-wide omnibus survey	June 2016
On-going reviews of evaluation evidence and routine data from NHSBT	Through to Spring 2017
Final analysis of the routine data	Summer 2017
Submission of agreed impact evaluation report and executive summary	September 2017
Publication of the report and summary	By the end of 2017

Annex 1: Main variables of interest

The analysis for the impact evaluation will follow the approaches outlined earlier in this document and in the interests of continued transparency further details will be published by the Welsh Government as the data is assessed. For the moment, we have listed some of the key variables that will be examined to assess the impact of the Act and this will be extended in due course, including more on the techniques employed in the evaluation, especially for analysis of the NHSBT data.

Necessarily, the variables are limited to those covered by the existing strands of the evaluation but could be supplemented by other data, such as from surveys carried out elsewhere in the UK. Data will also be examined in terms of themes (for example, awareness) across the different strands and will also look at how factors inter-relate (for example, increasing awareness and knowledge potentially leading to changes in attitudes and possible increases in the actual level of donation).

Table 3: Main variables of interest

ROUTINE DATA (all variables)
Gender
Age
Postcode/Borough
Wales or not
Quarter of Donation
Cause of Death
DBD donor
DCD donor
STAFF ATTITUDES (selected variables)
Awareness of change
Extent of knowledge
Levels of support or opposition
Attitudes to the new system
Role of the family
Impact on own job
Answering questions about the new system
Demographics (to differentiate views)
PUBLIC ATTITUDES IN WALES (selected variables)
Awareness of change
Levels of support or opposition
Intentions under the new system
Conversations with the family
Demographics (to differentiate views)