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Llywodraeth Cymru  
Welsh Government

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Vaughan Gething AC  
Cadeirydd, y Pwyllgor Iechyd a Gofal Cymdeithasol  
Cynulliad Cenedlaethol Cymru

1af Mai 2013

Annwyl Vaughan,

### **Strategaeth Werthuso ar gyfer y Bil Trawsblannu Dynol (Cymru)**

Mae adroddiad cyfnod un y Pwyllgor Iechyd a Gofal Cymdeithasol ar y Bil Trawsblannu Dynol (Cymru) yn argymhell: "y dylid cael strategaeth werthuso gadarn i gyd-fynd ag unrhyw newid o'r fath yn y trefniadau deddfwriaethol ar gyfer cydsynio. Byddai hyn yn darparu ffordd o fesur llwyddiant newid o'r fath a sylfaen dystiolaeth glir ar gyfer gwneud penderfyniadau polisi mewn lleoedd eraill".

Wrth roi tystiolaeth i'r Pwyllgor Iechyd a Gofal Cymdeithasol ar 20 Chwefror, dywedodd y cyn Weinidog Iechyd a Gwasanaethau Cymdeithasol fod swyddogion Llywodraeth Cymru yn gweithio ar strategaeth werthuso ac y byddai hon yn cael ei rhannu ag aelodau'r pwyllgor pan fydd yn barod. Er mwyn cyflawni'r ymrwymiad hyn ac er mwyn dangos y byddwn yn cyflawni'r argymhelliad i wneud gwerthusiad cadarn, amgaeaf y strategaeth werthuso er gwybodaeth i chi.

Yn gywir

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## **Human Transplantation (Wales) Bill: Evaluation Strategy**

### **1. Background**

The Welsh Government plans to introduce a soft opt-out system of organ donation through the Human Transplantation (Wales) Bill. The proposed legislation means that a person's consent to donation will be deemed to have been given unless they objected during their lifetime – a process called opting out – but where those closest to the deceased will still have an important role to play in the process. Subject to the will of the Assembly, the Welsh Government would expect the Bill to receive Royal Assent during summer 2013. It is anticipated that the main provisions of the Act will be brought into effect in 2015.

In order to assess the effectiveness of the implementation of the soft opt-out system of organ donation and the impact it has on donation and family consent rates in Wales, officials in Knowledge and Analytical Services have worked with the Bill team to develop a programme of evaluative research. This includes primary research with members of the public, Specialist Nurses, Clinical Leads, and other NHS staff; as well as making use of existing data through evidence reviews and analysis of routine data.

### **2. Aims and objectives**

The overall aim of the evaluation is to assess the implementation of the Human Transplantation (Wales) Bill and the impact it has on organ donation rates in Wales.

Specifically, the objectives of the evaluation are to:

- Use routine data to monitor changes in organ donation and consent rates over time;

- Assess the effectiveness and impact of the communications campaign on public attitudes towards 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);
- Synthesise and update international evidence on opt-out systems;
- Assess the implementation and impact that the legislation has on the work of Specialist Nurses and Clinical Leads (SNODs and CLODs), including feedback on training, and issues regarding family consent; and
- Monitor the attitudes of NHS staff involved in the referral process about the new law, its implementation and impact.

### **3. Methodology**

A programme of evaluative research is proposed that includes the following six strands:

- Strand one: impact evaluation
- Strand two: public attitudes survey (repeated at regular intervals)
- Strand three: qualitative research with the public
- Strand four: qualitative research with SNODs and CLODs
- Strand five: measuring NHS staff attitudes
- Strand six: additional components (including international evidence reviews)

These six strands are now discussed in turn. An overview of the evaluation strategy is attached at Annex A.

#### ***Strand one: impact evaluation***

The implementation of a soft opt-out system of organ donation in Wales, while the rest of the UK continues to operate an opt-in system, presents an opportunity to assess the impact of the Human Transplantation (Wales) Bill in

terms of a natural experiment. It takes place against a backdrop of an emerging UK strategy and further specific actions in each country of the UK. Therefore, it is planned that quantitative analysis of routine data on organ donation and family consent rates, using other UK countries as comparators, will be conducted over the stages detailed in Table 1, below.

**Table 1: Impact evaluation**

<b>Financial year</b>	<b>Stage</b>
2013-14	Analysis of trends to date and expected trends
2014-15	Follow-up measurements
2015-16	Follow-up measurements
2016-17	Follow-up measurements; emerging conclusions on impact; recommendations for future monitoring of data

A competitive tender exercise will take place in order to appoint an independent contractor to undertake this strand of the research. The successful contractor will be expected to:

- Agree outcome measures for determining the impact of the legislation;
- Monitor changes in outcome measures over time in Wales and the rest of the UK;
- Synthesise and summarise findings from the other research strands that constitute the overall evaluation to assess the success of the legislation; and
- Make recommendations based on the evaluation findings, including suggestions for any future research or long-term monitoring of data.

***Strand two: public attitudes survey***

The Beaufort Omnibus Survey is being used to collect data on public awareness and understanding of organ donation law, and attitudes to changes in the legislation in Wales. Data are being collected at regular intervals between 2012 and 2016 to support the ongoing implementation of

the legislation, as well informing the other strands of the evaluation. The analysis will also be used to inform how communications are targeted among different groups of the population.

Approximately 1,000 interviews are being carried out in each wave of the survey with a representative sample of the adult population of Wales. The dates for survey waves are detailed in Table 2, below.

**Table 2: Public attitudes surveys**

<b>Financial year</b>	<b>Survey waves</b>
2012-13	June 2012
2013-14	June 2013 and November 2013
2014-15	June 2014 and November 2014
2015-16	June 2015 and November 2015
2016-17	June 2016

While the data collection is commissioned, the analysis and report writing is carried out in-house by officials in Knowledge and Analytical Services. The findings report from the June 2012 baseline survey was published on the Welsh Government website in October 2012<sup>1</sup>.

A decision will be made at a later date as to how public awareness, understanding and attitudes are monitored post-2016.

### ***Strand three: qualitative research with the public***

In 2012, the Welsh Government commissioned Beaufort Research Ltd to undertake a qualitative research project with members of the public to support the Welsh Government's consultation on an opt-out system for organ

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<sup>1</sup> Welsh Government (2012). *Public attitudes to organ donation: Baseline survey 2012*. Available here: <http://wales.gov.uk/about/aboutresearch/social/latestresearch/publicattitudesorgandonation/?lang=en>

donation. The findings report was published on the Welsh Government website in April 2012<sup>2</sup>.

Building on this project, it is proposed that further qualitative research with members of the public takes place over three stages, as outlined in Table 3, below.

**Table 3: Qualitative research with the public**

<b>Financial year</b>	<b>Focus</b>
2013-14	To explore findings emerging from the ongoing surveys of public attitudes in greater depth prior to the legislation coming into effect
2014-15	Primarily to test effectiveness of communication materials
2016-17	To explore findings from the surveys of public attitudes in greater depth following the implementation of the legislation

A competitive tender exercise will take place in order to appoint an independent contractor to undertake this strand of the research. The contractor will be expected to use qualitative research techniques to collect and analyse data on the views of the public regarding organ donation in Wales and the implementation of a soft opt-out system. For the data collection, this may involve one-to-one interviews, focus groups, or a combination thereof.

#### ***Strand four: qualitative research with SNODs and CLODs***

Qualitative research with SNODs and CLODs is taking place over three stages, as outlined in Table 4, below.

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<sup>2</sup> Beaufort Research Ltd. *Research to support Wales' organ donation opt-out proposal consultation*. Available here: <http://wales.gov.uk/about/aboutresearch/social/latestresearch/organdonation/?lang=en>

**Table 4: Qualitative research with SNODs and CLODs**

<b>Financial year</b>	<b>Stage</b>
2012-13	Prior to passing of Bill
2014-15	Run up to implementation of Act
2016-17	Post-implementation of Act

This strand of research will assess the preparedness of SNODs and CLODs, identify their needs, and provide an in-depth understanding regarding the role of the family in organ donation. It will also complement other strands of the research in assessing the extent that organ donation is becoming viewed as a norm – in hospitals, and among families of potential donors – before and after the implementation of the legislation.

In December 2012, the Welsh Government commissioned Beaufort Research Ltd to undertake the first stage of this strand of research. Data collection took place during February and March 2013, and involved in-depth interviews and online group discussions with SNODs and CLODs across Wales. The final report is due to be published on the Welsh Government website in June 2013.

A competitive tender exercise will take place in order to appoint an independent contractor to undertake the next two stages for this strand of the research.

#### ***Strand five: measuring NHS staff attitudes***

In addition to the impact on the work of SNODs and CLODs, the implementation of a soft opt-out system will also have consequences for the work of other NHS staff in Wales, for example, transplantation teams; staff working in critical care services or emergency medicine departments; GPs; and administrative staff.

In order to monitor their attitudes, expectations and understanding regarding the implementation and impact of a soft opt-out system, it is proposed that a survey is conducted over two waves, as detailed in Table 5, below.

**Table 5: Measuring NHS staff attitudes**

Financial year	Stage
2013-14	Baseline measures prior to implementation of a soft opt-out system
2016-17	Follow-up measures following implementation of a soft opt-out system

A competitive tender exercise will take place to appoint an independent contractor to undertake this strand of the research. It is expected that the contractor will use quantitative research techniques to collect and analyse data on NHS staff attitudes, expectations and understanding regarding the implementation and impact of a soft opt-out system.

***Strand six: additional components***

A number of additional small-scale research projects will be required over the course of the evaluation. As such, this strand of the evaluation strategy is designed to be more flexible in order to respond to additional research needs, should they arise.

The research projects that have been carried out to date as part of this strand, both through the ESRC-Welsh Government PhD internship scheme, are as follows:

- An international evidence review of opt-out systems of organ donation, published in December 2012<sup>3</sup>; and
- An international evidence review of the role of families in organ donation, published in December 2012<sup>4</sup>.

Further projects currently planned under this strand are as follows:

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<sup>3</sup> Welsh Government (2012). *Opt-out systems of organ donation: International evidence review*. Available here: <http://wales.gov.uk/about/aboutresearch/social/latestresearch/optoutorgandonation/?lang=en>

<sup>4</sup> Welsh Government (2012). *The role of families in organ donation: International evidence review*. Available here: <http://wales.gov.uk/about/aboutresearch/social/latestresearch/familiesorgandonation/?lang=en>



- Analysis of regional media coverage of organ donation (to further explore findings from the baseline survey of public attitudes). Swansea Metropolitan University have been commissioned to undertake this project, and a report is due to be published on the Welsh Government website in July 2013.
- A literature review of existing research on the interplay between faith, ethnicity, culture and organ donation, considering in particular any issues relating to the introduction of an opt-out system of donation and issues relating to family consent rates. This is due to be conducted during 2013-14.

#### **4. Outputs**

Research reports and executive summaries for each strand of the evaluation will continue to be published on the Welsh Government website, in line with the Government Social Research publications protocol. Under the protocol, we are required to publish research outputs within 12 weeks of agreeing a final draft.

As part of strand one of the research – the impact evaluation – the contractor will produce a final report that will synthesise findings from the other research projects that make up the overall evaluation. This final report will also make recommendations for future research and monitoring of data. It is envisaged that the final report will be made available in March 2017, although a series of interim reports will also be produced.

**Ian Jones**

Knowledge and Analytical Services

April 2013

## Annex A: Overview of evaluation strategy

	2012-13	2013-14	2014-15	2015-16	2016-17
<b>Strand one: Impact evaluation</b>		Analysis of trends; expected trends; and setting outcome measures	Follow-up measurements	Follow-up measurements	Follow-up measurements; emerging conclusions on impact; recommendations for future monitoring
<b>Strand two: Public attitudes survey</b>	Data collection: June 2012 (Report to follow in September 2012)	Data collection: June 2013 and November 2013 (Reports to follow at later date)	Data collection: June 2014 and November 2014 (Reports to follow at later date)	Data collection: June 2015 and November 2015 (Reports to follow at later date)	Data collection: June 2016 (Report to follow at later date)
<b>Strand three: Qualitative research with the public</b>	Bill consultation stage	Explore emerging findings from public attitudes survey (pre-implementation of legislation)	Test effectiveness of communications materials		Explore findings from public attitudes survey (post-implementation of legislation)
<b>Strand four: Qualitative research with Specialist Nurses and Clinical Leads</b>	Pre-legislation stage		Mid-point stage		Post-legislation stage
<b>Strand five: Measuring NHS staff attitudes</b>		Baseline measurements			Follow-up measurements
<b>Strand six: Additional components</b>	Evidence reviews of opt-out systems and role of families.	Analysis of regional media coverage; literature review of interplay between faith, ethnicity, culture and organ donation	TBC	TBC	TBC