



Proposed Organ and Tissue Donation (Scotland) Bill

Response from British Heart Foundation Scotland

September 2014

The current organ donation system simply doesn't work. Despite decades of campaigning to encourage people to join, and the fact that 90 per cent of the public say they support organ donation, the number of people on the register remains at only 32 per cent across the UK.¹

- **Nearly 7,000 people in the UK are waiting; the need for organs greatly outweighs the availability.** In the UK, three people die every day in need of an organ, a needless loss of life that could be avoided by a simple change in the system.²
- **Scotland is the country with the highest proportion of registered organ donors in the UK with 40 per cent of the population in 2013/14.** It does however have the **second lowest donation rates out of the 4 nations with only 20.3 donations per million people which is below the total across the UK as a whole which is 20.6 people per million.**³
- **Over 41 per cent of families in 2013/2014 refused organ donation because they don't know what their relative's wishes were.**⁴
- **Our rate of organ donation is low compared to many other European countries.**⁵
- **In 2013/2014 Scotland had an eligible donor rate of 61.8 per million population (pmp) equating to 328 possible donors.** The average donor in Scotland donated 3.5 organs in 2013/2014 representing a **potential 1148 organs available for transplant.** The reality in Scotland was however only 20.3 pmp of the eligible donors went on to donate.⁶
- **Not all people die in circumstances that can allow for organ donation however in 2013/2014, two thirds of eligible donations in Scotland did not occur resulting in a missed opportunity to save a life.**

¹ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

² NHS Blood and Transplant website (2014)

³ All figures for 2013/2014; http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

⁴ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

⁵ European Parliament (2007)

http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/docs/fact_figures.pdf

⁶ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

British Heart Foundation Scotland (BHF Scotland) is the nation's leading heart charity. We are working to achieve our vision of a world in which people do not die prematurely or suffer from cardiovascular disease. In the fight for every heartbeat we fund ground breaking medical research, provide support and care to people living with cardiovascular disease and advocate for change.

We would like to take this opportunity to thank Anne McTaggart MSP for the opportunity to respond to this public consultation and for undertaking the work to bring this issue to the Scottish Parliament. The British Heart Foundation has been working across the United Kingdom to support the work of government and parliamentarians on the issue of organ donation and we are delighted to be involved in the conversation now taking place in Scotland.

The following response will answer the question posed by the consultation in the order in which they appear in the consultation document.

Q1 Do you support the over-arching purpose of the proposals?

BHF Scotland fully supports the overarching principle of the proposals laid out in the consultation document.

We know that nine out of ten people in Scotland⁷ support organ donation, but less than 40% have actually joined the Organ Donation Register⁸. There is clearly a yawning gap between good intention and action. As the nation's heart charity, BHF Scotland is committed to increasing the rate of organ donation. Promoting organ donation is vital but on its own will not deliver the much needed increase in organs.

BHF Scotland supports the following three calls:

- Changing the system of registration from opt-in to soft-opt out
- Continued investment in infrastructure and staff training
- Encouraging families to have open conversation about organ donation

The Organ Donation Taskforce set a target in 2008 to increase donation that would result in an additional 1,200 transplants a year across UK by 2013. While the number of donors has increased in the last five years, the expected rise in additional transplants has not been achieved. Even if this had been met people would still be dying unnecessarily whilst on the waiting list.⁹

A Positive Change

The move to a soft-opt out system of organ donation is a minor yet positive change to how we conduct organ donation in Scotland. It is simply a shift in emphasis to a positive and proactive approach. Under opt-out there is no compulsion to donate and those who don't want to donate can express their wishes not to.

⁷ <http://bma.org.uk/working-for-change/improving-and-protecting-health/organ-donation/scotland>

⁸ <http://news.scotland.gov.uk/News/Donor-and-transplant-rates-soar-b58.aspx>

⁹ Organ Donation Taskforce (2008) The potential impact of an opt-out system for organ donation in the UK

Bridging the Gap -

There is a need to bridge the gap between donation rates and transplant rates. It is important to remember that organ donation and transplantation is UK wide and organs from deceased people in Scotland are used across the country, likewise organs transplanted in Scotland may have come from other parts of the UK. Therefore in discussions on rates we will look at the picture in Scotland but also across the UK.

In Scotland in 2013/2014 a total of 342 donations were transplanted using deceased donors whilst there was 595 patients waiting on the transplant list.¹⁰ That represents a needs gap of 252 transplants. Whilst these figures are indicative of 2013/2014 it is important to note that demand fluctuates year on year.

Across the UK the picture is similar with 3512 transplants involving deceased donors and a total of 7026 patients actively awaiting transplant; representing a shortfall of 3514 transplants.¹¹

The current organ donation system simply doesn't work. Despite decades of campaigning to encourage people to join, and the fact that 90 per cent of the public say they support organ donation, the number of people on the register remains at only 32 per cent across the UK.¹²

- Nearly 7,000 people in the UK are waiting; showing that the need for organs greatly outweighs the availability. In the UK, three people die every day in need of an organ, a needless loss of life that could be avoided by a simple change in the system.¹³
- Scotland is the country with the highest proportion of registered organ donors in the UK with 40 per cent of the population in 2013/14. It does however have the second lowest donation rates out of the 4 nations with only 20.3 donations per million people which is below the total across the UK as a whole which is 20.6 people per million. The total potential donor rate in Scotland, if all potential donors went on to donate, is 61.8 people per million population.¹⁴
- The Organ Donation Taskforce held seven one-day workshops to gauge public views on an opt-out system for organ donation. Before the events 65 per cent of people supported a change in the law, after receiving information and considering the issue in detail, support rose to 72 per cent and strong support rose from 25 per cent to 43 per cent.¹⁵
- Over 41 per cent of families in 2013/2014 refused organ donation because they don't know what their relative's wishes were.¹⁶

¹⁰ http://www.organdonation.nhs.uk/statistics/downloads/scotland_july14.pdf

¹¹ http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_july14.pdf

¹² http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

¹³ NHS Blood and Transplant website (2014)

¹⁴ All figures for 2013/2014; http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

¹⁵ Organ Donation Taskforce (2008) *The potential impact of an opt-out system for organ donation in the UK*

¹⁶ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

- Our rate of organ donation is low compared to many other European countries.¹⁷

Learning from other countries –

Spain has the highest levels of donations per million population in the world and introduced an opt-out system in 1979, although in practice organs are only ever extracted with the consent of families. Much of the success in Spain is attributed to a transplant co-ordinator network operating at national, regional and hospital level. There has been considerable investment in training of healthcare professionals and organ donation has been integrated into mainstream intensive care, rather than being superimposed onto it.¹⁸ The mass media has also been used as a vehicle to provide information to the public about organ donation.

In **Belgium**, an opt-out system was introduced in 1986 and there are eight transplant centres across the country. Families are informed and can opt-out. The major cause of organ donor loss is low detection and a new law is being developed that will create a legal obligation for healthcare professionals to ensure that every patient entering the imminent death pathway is considered as a potential donor. The care of donors has also been professionalised through identifying 'donor communicators' in each unit and putting in place protocols for staff to follow.

In **Norway** an opt-out system has been in operation since 1973 although there is no register in place and families can refuse. There is a single transplant centre in Oslo which is the largest facility in Europe and has five transplant co-ordinators. There is a national training programme for healthcare professionals in place and national protocols governing donation.

Q2 How essential is it to change the law in order to achieve the intended benefits? Are there other (non-legislative) measures that could achieve similar outcomes without the need for legislation?

BHF Scotland believes that the time has come to enact a change in law to support the outcomes required. Whilst we recognise the great work undertaken by Government and other agencies, including BHF, to promote sign-up to the organ donor register the needs gap is still too great and resulting in needless loss of life.

Across the UK we have seen an increase in 1 per cent per year on year since 2010/2011¹⁹ of people registered as organ donors. This has resulted in 802 more transplants from deceased donors an average of 267 transplants per year. To close the gap at the current rate of increase and demand it would take 13 years.²⁰

¹⁷ European Parliament (2007)

http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/docs/fact_figures.pdf

¹⁸ Van Gelder F et al (2008) What is the limiting factor for organ procurement in Belgium; donation or detection? What can be done to improve organ procurement rates? Acta chir belg, 2008, 108, 27-30.

¹⁹ http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_july14.pdf

²⁰ http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_july14.pdf

In 2013/2014 Scotland had eligible donor rate of 61.8 per million population (pmp) equating to 328 possible donors. With the average donor in Scotland donating 3.5 organs in 2013/2014 that is a potential 1148 organs available for transplant.

The reality in Scotland was however only 20.3 pmp, a total of 108 deceased donors.²¹ Not all people die in circumstances that can allow for organ donation however the reality is in Scotland two thirds of eligible donations do not occur resulting in a missed opportunity to save a life.

Q3 Do you agree family consent should be limited to being consulted on whether they are aware of any (unregistered) objections by the deceased rather than asking for their consent.

BHF Scotland supports a soft-opt out system because it maintains the role of the family in the decision making process.

The BHF believe that the rights of the deceased are paramount. We also believe that the family have an important consultative role at the point of organ retrieval. We believe the families' role is to ensure that any unregistered wishes of the deceased are known to health professionals.

Family rejection rates however are stubbornly high at 41% in the UK²² and NHS Blood and Transplant stated that *"deaths among patients who are in need of a transplant will sadly be unavoidable while the consent / authorisation rate for deceased organ donation remains lower than many other countries in the western world. Although the consent/authorisation rate increased slightly from 57% in 2012/13 to 59% in 2013/14, we have to make huge strides if we are to achieve the ambitious 80% target by 2020,"*²³ clearly highlighting the challenge we face.

We know that when the family are aware of the deceased wishes that the familial refusal rate plummets to 11.6%.²⁴ Therefore highlighting how important it is for people to have the conversation with their loved ones and make their wishes known. We believe that changing the way we register consent to a soft opt-out system can offer a population wide opportunity for this conversation and help make a a difficult decision at a difficult time easier.

²¹ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/

²² http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2013_14.pdf

²³ Ibid

²⁴ http://www.organdonation.nhs.uk/statistics/transplant_activity_report/archive_activity_reports/pdf/ukt/activity_report_2012_13.pdf

Q4 Do you think an individual should be able to appoint a proxy to make the final decision regarding transplantation on their behalf?

In a modern society it is understandable that an individual may be distanced or no longer in touch with family members and therefore the family may not be the best people to make the decision for them. If someone feels that they would like to nominate someone who is outside of their family unit and more likely to support their wish then this option should be available.

Q5 Only adults should be automatically opted in to be donors. Younger persons would have to register to be a donor.

BHF Scotland fully supports this and it is consistent with other practices in organ donation across the UK and Europe.

Q6 The age limit for an adult should be set at 16 years old

BHF Scotland agrees that the age limit to determine an adult is set at 16 years old and is in line with the Age of Legal Capacity (Scotland) Act 1991.²⁵

BHF Scotland would also been keen to see that those individuals under 16 have an opportunity to actively register their wishes. There is currently no age limit for organ donation and whilst presumed consent should only start at the age of 16 those individuals below that age who wish to register should be allowed to.

Q7 Do you agree the soft-opt out system should apply to people who have been resident in Scotland for a minimum of 1 year prior to their death?

BHF Scotland believes that a minimum period of 1 year residency is acceptable and is in accordance with similar legislation within the UK.

The Human Transplantation (Wales) Bill allows exception for "an adult who has and who had not been ordinarily resident in Wales for a period of at least 12 months immediately before dying."²⁶

Q9 Do you think 6 months is long enough to run a campaign before the change over?

²⁵ <http://www.legislation.gov.uk/ukpga/1991/50/section/1>

²⁶ Human Transplantation (Wales) Act; Section 5 "Consent excepted adults"
<http://www.senedd.assemblywales.org/documents/s18988/Bill.%20as%20passed.pdf>

BHF Scotland believes it is important to have a period before the change over for public information campaigns to ensure the general public are ready for the change. It would be prudent to assess similar campaigns such as that carried out in Wales ahead of the switch to soft-opt-out in 2015.

Q10 What is your assessment of the likely financial costs for your organisation?

The Bill would not have any financial implications for BHF Scotland however the following analysis can be offered for heart transplants.

Although heart transplants are expensive treatments the benefits to be gained by patients who receive transplants are priceless, such as an extension of their life, an improved quality of life and removal from medical management of their condition. Together these provide 'favourable cost effective ratios' for heart transplantation.²⁷

A cost-benefit analysis model conducted in Wales as part of the legislation to introduce soft opt-out shows that transplantation under an opt-out system is a cost effective treatment option, and would in effect 'more than pay for itself.'²⁸ This is based on the conservative assumption that a change of system would generate just one additional donor per year.

Across all organs this would see a saving of £3million in the first year set against the costs of implementing the system change. There are a number of projections as to the extent to which rates of organ donation are likely to increase following the introduction of an opt-out system. One study suggests that rates could increase by 25-30%.²⁹ This would mean an approximate increase of 15 donors in Wales per year, offering significant financial benefits. Expanding this model and projection to the UK would see a potential increase of between 330 and 396 donors in the UK as a whole representing large cost savings to the healthcare system.³⁰

For heart transplants this analysis also estimated that over a ten year period – the average survival time for heart transplant patients – there would be a net benefit of £2.4 million per transplant.³¹ This includes a saving of £50,000 per patient, over ten years as a result of removing the need for medical management.³² This figure also takes into consideration the improvement of life quality each transplant patient would experience, calculated through Quality Assured Life Years (QALY).³³

²⁷ NICE 'Guideline No.5 Chronic Heart Failure: National clinical guideline for diagnosis and management in primary and secondary care.'
http://www.nice.org.uk/nicemedia/pdf/Full_HF_Guideline.pdf

²⁸ Welsh Government (2012) *Human Transplantation (Wales) Bill Regulatory Impact Assessment.*

²⁹ Abadie A and Gay S (2004) 'The Impact of Presumed Consent Legislation on Cadaveric Organ Donation.'

³⁰ BHF estimate based on 1,320 donations as cited in NHS Blood and Transplant (2014) *Transplant Activity Report 2013/14'*
http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/000/activity_report_2013_14.pdf

³¹ Welsh Government (2012). *Human Transplantation (Wales) Bill: Explanatory Memorandum'*

³² Welsh Government (2012) *Human Transplantation (Wales) Bill Regulatory Impact Assessment.*

³³ QALY: A measure of health status in terms of the quality of life associated with a state of health, and the number of years for which that health status is enjoyed. Using the Department of Health's measurement that 1 QALY equates to £60,000.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216003/dh_120108.pdf

The benefits in QALYs from a successful donation are significant; patients who receive donor hearts can see their life expectancy increase from only 1.5 years on medical management, to an average survival time of ten years.³⁴ For those with critical heart failure, a heart transplant is their only treatment option. There will also be significant psychological gains for patients that no longer have to receive on-going medical management and have the peace of mind of longer term survival

Q11 Is the bill likely to have any positive or negative implications for equality?

BHF Scotland does not foresee any negative equality issues. This Bill only seeks to change the method in which you register as a donor. We believe that the soft-opt out system will protect cultural objections to organ donation through the retention of the family's role after death.

The Bill would only alter the process in which individuals become organ donors and register their objections.

If the change to soft-opt out was to be successful the ensuing publicity campaign would be required to engage with all members of society to promote the change and educate the public. This campaign would have to ensure that all sections of society were catered for and therefore allow for more engagement with communities that haven't traditionally responded to current organ donation campaigns.

Should the Bill be successful it would be a further platform to engage with Black and Ethnic Minority communities across Scotland on the issue of organ donation. BME communities in the UK are more likely to need an organ yet have significantly lower rates of donation than the UK white population. For example people of Black and South Asian communities are three times more likely to need an organ transplant.³⁵ This group represents 7.8% of the UK population³⁶ but only make up 2% of the organ donor register.³⁷ Research shows³⁸ that there are a number of reasons for this low donation rate:

- **Religious belief** – although none of the major religions in the UK oppose organ donation, there are concerns surrounding donation harming one's body and that donation would hinder the respected quick burial ritual followed in some religions.
- **Lack of conversation** – there is a great reluctance amongst some BME communities to discuss death. This is believed to be inappropriate and tempting fate, and therefore results in many dying without their family knowing their wishes.
- **Anxieties and myths of organ donation** – research has shown that the most common barrier to organ donation in BME communities is lack of information surrounding organ donation including how to become a donor. There is also distrust of doctors to do their best to prolong your life if they know you are on the organ donor

³⁴ Welsh Government (2012) *Human Transplantation (Wales) Bill Explanatory Memorandum.* Pg. 48.

³⁵ NHS Blood and Transplant (2013) Campaign materials. <https://ww3.access-24.co.uk/Stock.aspx?G0=Group1&G1=2733>

³⁶ ACORN Statistics <http://acorn.cacl.co.uk/>

³⁷ NHSBT Campaign materials

³⁸ Sims, J et al. (2012). 'Overcoming barriers to registering as an organ donor among minority ethnic groups.' *Race Equality Foundation.* <http://www.better-health.org.uk/briefings/overcoming-barriers-registering-organ-donor-among-minority-ethnic-groups>

register. There is also concern around the process of organ removal and if this would distress families where an open casket funeral was the norm.

Conclusion –

BHF Scotland would like to take the opportunity to thank Anne McTaggart MSP and her team for the opportunity to respond to this consultation. The BHF has campaigned across the UK for a change to soft-opt out for a number of years and welcomes the developments in Scotland.

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