Dear Mr McNeil,

I am writing to provide some clarification on the issues raised by the Scottish Government in its evidence to you on the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill.

Consultation with experts

The Scottish Government has recommended that I actively seek information and evidence from the key expert organisations and individuals working in the area of organ donation. Firstly, let me reassure the Committee that when drafting this Bill and considering the policy I sought information from a number of health professionals, including experts working in the area of organ donation. In particular the British Heart Foundation and the British Medical Association. Throughout this process I have also continued to consult with Dr. Barbara Neades, Senior Lecturer at Edinburgh Napier University School of Nursing Midwifery and Social Care. Dr Neades has many years of experience of working with specialist nurses for organ donation and helped to shape UK transplant policy.

Recent Achievements

The Scottish Government has provided some data on organ donation and transplant rates and the number of people on the Organ Donor Register. This data compares current figures with those of 2007/2008. The data gives the impression that the Scottish Government’s strategy is working and that it is on a trajectory to meets its 2020 targets. This is not necessarily the case. In the past year:

- deceased donor rates fell by 7.5%
- the number of deceased donor transplants fell by 13%
- second quarter figures for this year indicate there might be a 16% decrease in deceased donor rates for 2015 /16
- family refusal rates were 46.1%, an increase of 7%.
Evidence from other countries

The policy memorandum includes the most up-to-date data on deceased organ donation rates available at the time of publication. Paragraph 19 states that this was “21 donors per million population (pmp)” in 2013. For comparison purposes it also includes the 2007-08 figure of 12.9 pmp in paragraph 19 and describes the change since then as a “significant increase”.

The Scottish Government states “that the organ donor rate in the UK is now significantly higher than those 2007/8 figures and is now, at 21 pmp, roughly comparable with most of these countries”. I assume this refers to the deceased organ donor rate. This is an accurate figure for the UK; however, according to the latest information published by NHSBT\(^1\) the deceased organ donation rate for Scotland is now 18.2 pmp. This rate compares poorly with other European countries. The Scottish Government has set a target to increase overall deceased donation rates from 17.9 per million population in 2012/13 to 26 per million population by 2020. In the past three years this rate has only increased by 0.3 pmp.

Spain

Spain continues to have the highest organ donation rates in Western Europe. There are differing views on what has contributed to this success. Some attribute it to having an opt-out system of organ donation whilst others have found that it is attributable mostly to improvements in its donation and transplantation infrastructure and education and public awareness-raising. I see these as being complementary and all three are necessary components to successfully implementing a soft opt-out system.

The Organ Donation Taskforce found, in its publication ‘The potential impact of an opt out system for organ donation in the UK’, this to be the case in Tuscany:

“11.4 In Italy presumed consent legislation was passed in 1999, but before it was fully enacted some regions, notably Tuscany, adopted the Spanish organisational model and saw organ donation rates double to 26.9 donors per million population.”\(^2\)

The majority of international studies have focussed on the impact of opt-out systems on deceased donor rates. Whilst the British Medical Council research panel paper (referred to by the Scottish Government) found that an opt-out system “may lead to an increase in deceased donation but a reduction in living donation rates” it also described this latter impact as “non-significant”.

\(^1\)Organ Donation and Transplantation Activity Report 2014/15, page 7.

\(^2\)The potential impact of an opt out system for organ donation in the UK, page 22.
Calculating Increases to the Donation and Transplant Rates

Paragraph 25 of the policy memorandum indicates that an increase in donation rates of 25–30% is expected when an opt-out system is introduced. Taking the 2014–15 figure of 98 deceased donors in Scotland this would mean an increase of between 24 and 29 donors.

The analysis provided by NHSBT is welcome. Using the same methodology that was used to calculate the estimated increase in Wales, NHSBT found that there “might be up to 39 additional organ donors in Scotland” as a result of the implementation of a soft opt-out system. It is a little unclear why NHSBT thinks the increase would be as high as 39%, but as they are the experts in this area I am willing to accept their estimate.

According to the Scottish Government, one of NHSBT’s assumptions, in making that estimate, was that “hospitals are already fully set up to deal with any increase [in donor and transplant rates]”, and the Scottish Government describes this as “untested”. This is inaccurate. The Scottish Government has undertaken a great deal of work to ensure that resources are in place to meet the targets it has set in: ‘A donation and transplantation plan for Scotland 2013-2020’. For example, appointing an additional seven Specialist Nurses for Organ Donation in critical care areas.

In its submission to the Finance Committee, on the Bill’s financial memorandum, the Scottish Government explained that NHS National Services Division had undertaken a great deal of work to forecast the potential costs of additional transplants arising out of its 2013-2020 Plan and confirmed that it had also “undertaken detailed consultation with NHS Boards to ensure resources will be made available to support these additional costs.”.³

NHS National Services Division, in its submission to the Finance Committee, confirmed that any additional costs related to the implementation of the Bill would be met, stating that “if there were to be an increase in transplantation activity as a result of the Bill, National Services Division would expect to manage this within the existing financial portfolio”.⁴

Registering an Objection to Organ Donation

The Scottish Government is of the view that section 1 of the Bill, which requires Scottish Ministers to ensure registers approved by them are in place to enable an adult (of 16 years or over) to register an objection, is not needed as they can already register an objection on the Organ Donor Register. However, registering an opt-out decision on the Organ Donor Register does not provide any legal guarantee that such an opt-out is adhered to. This should be the basis for any opt-out system in Scotland.

³ Scottish Government submission to the Finance Committee, page 8.
⁴ NHS National Services Division submission to the Finance Committee, page 2.
The Scottish Government also suggests that the 2006 Act enables an adult to withdraw authorisation for donation and that this does not require a positive authorisation to have been given previously. But section 6 of the 2006 Act is not an opt-out provision. If no authorisation had been previously given, there would be nothing for the adult to withdraw under that section.

**Sixteen Years and Over**

The age limit of 16 is set in the Bill as this is the age at which people acquire many other legal rights. They are old enough to fully understand their legal obligations in terms of opting-out of organ donation or making no choice.

As noted above, the new opt-out option in the online Organ Donor Register has no legal status. The Human Tissue (Scotland) Act 2006 remains the legislative basis for organ donation in Scotland, and sets out the requirements for an opt-in system; nothing in the Act currently provides a legal basis to opt out. The Bill would do exactly that, but would not take away any existing rights that children have – including the right to opt in under the 2006 Act, or the new ability to record an opt-out in the online ODR.

**In the Event of a Change of Mind**

The Scottish Government is of the view that contacting the next of kin “automatically allows for an assessment of the deceased’s most recently expressed wishes”. As the Committee has heard, this is not always the case – the relatives (if any) who can be contacted may not know about the deceased person’s wishes, or may misrepresent those wishes to NHS staff (inadvertently or deliberately – for example, if the relative’s personal view is strongly at odds with that of the deceased person). It is partly for this reason that the Bill provides adults with the option of appointing up to three proxies. This lets them choose the people who they wish to make decisions on their behalf. There is nothing to prevent a proxy being a close family member, but it could also be someone entirely unrelated to the adult – if, for example, the adult trusts that unrelated person more than a family member.

Under the current opt-in system if a person has agreed to donate their organs, for example by registering on the Organ Donor Register, the family has no legal right to veto or over-rule the person’s wishes – although in practice the relatives are always consulted.

**Not ‘Getting Around’ to Registering**

A key purpose of the Bill is to encourage people to have a conversation with those closest to them so that they know their wishes and so are more likely to respect them if the issue of deceased organ donation arises. This is to reduce the instances of family members having to make a personal decision on organ donation at the most distressing of times. Family refusal rates in Scotland are increasing. The Bill and the accompanying publicity campaign aim to encourage people to register their view, so that the number of those not getting around to registering should be reduced.
Presumed Consent After Six Months Habitual Residency

The Bill contains a 6 month period of habitual residency in Scotland as I consider this a sufficient period of time for adults to be made aware of the change to the law on organ donation and to opt-out if they wish to do so. If this is not seen as a sufficient length of time I would be happy to consider other views.

The Scottish Government suggests there are “additional implications and significance” for international students and others who have recently moved to Scotland from overseas. I recognise that moving to a foreign country carries with it a lot of legal consequences, but it is the responsibility of any person in that situation to familiarise themselves with the laws of the country that they are living in. The initial publicity campaign and the annual high-profile campaigns will ensure that the public are aware of the soft opt-out system of organ donation.

Rebuttable Presumption

Determining whether an adult had a reasonable opportunity to opt-out is part of the sensitive conversation that the health professionals will have with proxies and family members. The Human Tissue Authority provides a detailed code of practice for health professionals to assist them in implementing the different legislative approaches to organ donation in England, Wales and Northern Ireland. To accompany the Welsh Bill it produced a detailed code of practice which included different scenarios that health professionals might face to assist them in deciding on deemed consent and the correct conclusions to draw. This is currently in draft form and a final version will be available in December 2015. I would expect the Scottish Government to provide similar material to accompany the implementation of this Bill.

Proxy Precedence Over Next of Kin and ECHR Implications – Article 8

The proxy provisions have been carefully designed to ensure that, where there is an appointed proxy, this does not cause additional delay to the process. Allowing up to three proxies was intended to maximise the chances that at least one will be contactable within the limited time-frames involved – but this could easily be reduced to two if that is considered a more practical balance.

The rest of the UK has had proxies since the Human Tissue Act 2004 was implemented in 2006 (although it uses the term ‘nominated representatives’). The Bill aims to provide this option to people in Scotland also. It adopts a similar process to that of the rest of the UK, where nominated representatives (where appointed) are contacted first and where, if they give consent, this cannot be overridden by other individuals, including family members. This system has been in operation for almost 10 years and I am unaware of any legal challenges during that time under Article 8 of the European Convention on Human Rights.

A proxy can be any adult that the individual chooses, including family members and health professionals. If a health professional had a conflict of interest, their code of ethics would preclude them from taking on this role.
Will Proxies Work, in Practice?

The Scottish Government is no doubt correct to say that in “most instances” only nearest relatives will be able to provide important information about health, family history etc., but this is not true in all instances (e.g. where the deceased has no close family, or is estranged from them). In any case, the Bill does not rely on proxies providing factual information of this sort. The only role of a proxy (where they have been appointed – which is likely to be the case in only a small number of cases) is to make the decision whether or not to authorise the removal of organs for transplantation; the AIP will still be consulting nearest relatives in any event, so can still ask them about the deceased person’s health, lifestyle etc. More generally, as mentioned above, giving a role to proxies is a tried and tested part of the system which has worked well in the rest of the UK for a number of years.

Where a proxy is appointed, he or she is empowered by the adult to make decisions on their behalf and therefore, where the proxy is not himself or herself a close relative, those relatives would have no legal right to over-rule the proxy’s decision. This is similar to current legislation where the family has no legal right to over-rule a deceased person’s decision to donate. However, as the Scottish Government point out, in practice clinicians take into account the feelings of families and whether the decision to donate would cause them great distress. Whilst respecting the person’s own wishes (which may include putting the decision in the hands of a trusted proxy) is important, I would expect clinicians to adopt a similar approach to implementing this Bill.

Practical Impact of Checks by the AIP

The aim of the Bill is to greatly increase the proportion of cases where a deceased person is a prospective donor. This requires some additional safeguards to provide checks and balances, and every effort has been made to provide a practical and proportionate process that takes account of the often time-critical nature of transplantation.

Health professionals already carry out a number of the tasks that are required by the Bill, such as checking the Organ Donor Register for an opt-in or opt-out decision and contacting relatives. The Bill requires them to contact proxies, whose details are on the Organ Donor Register, and if they are not immediately available, to wait a reasonable time for a response. What amounts to a “reasonable time” is determined by the AIP taking account of the timescales in which decisions must be made if the organ is to be transplanted. If time is of the essence then it will be possible for the AIP to move on to the next proxy on the list or nearest relative very quickly.

These are tasks that health professionals already carry out in the rest of the UK and I am not aware of any evidence that this has slowed down the process or impacted on the number of organs being transplanted.
Authoriser or Investigator

Under the new section 6B procedure, the AIP has a role in determining whether the removal of organs is lawful; but in such a case the source of authority for that removal is the law itself, not the AIP. The AIP is given a procedure to follow and criteria to apply; some of these require judgements to be made, but that is inevitable in this context, and is already part of what NHS staff do in many end of life situations.

It is also important to stress that the Bill, by introducing the term “authorised investigating person”, does not create a whole new role, but instead gives a convenient label to whichever staff are required to carry out the relevant functions. It is for Scottish Government and the NHS to decide which staff, and at what grades, are best suited to carry out these functions, many of which are similar to functions already performed on a regular basis by existing staff. The Bill deliberately provides that flexibility. It is also for the Scottish Government and the NHS to decide what support systems are needed for AIPs, to ensure that they are comfortable with the decisions they are taking. A detailed code of practice could assist in this regard.

The final decision on whether organs are to be removed would be taken by a senior clinician on medical grounds, once the AIP has confirmed that the legal requirements are satisfied.

Opt-Out Register

This Bill and the 2006 Act both allow for electronic registration. The Bill requires Scottish Ministers to approve an opt-out register, and since the existing UK-wide Organ Donor Register has already been adapted to accommodate the Welsh opt-out legislation, it seems likely to be suitable for approval by Scottish Ministers for the Bill’s purposes.

Awareness Raising

The Bill requires the Scottish Government to undertake a publicity campaign of at least 6 months. As outlined in my letter to the Finance Committee of 29 October 2015, copied to the Health and Sport Committee, I am content with the Scottish Government’s proposal for a one or two year campaign at a cost of £3.3 million.

Costs for a recurring publicity campaign were not included in the Bill or financial memorandum as the Scottish Government allocates an annual organ donation advertising budget to fulfil its obligation under section 1(1)(b) of the Human Tissue (Scotland) Act 2006 to: “promote information and awareness about the donation for transplantation of parts of a human body”.

Adults with Incapacity under a Presumed Consent System

The Scottish Government raises a concern that the provisions in section 6B may have the unintended consequence of adults with incapacity becoming ‘locked-in’ to organ donation. This is not the case.
Under section 6B, the AIP must satisfy themselves “that the adult had a reasonable opportunity to record an objection to such removal and use” of their organs. As noted in the Policy Memorandum, a lack of capacity over a substantial period is just the sort of factor that could lead the AIP to conclude that a person lacked a reasonable opportunity to object – and so prevent the removal of organs being authorised.

Currently, the relatives, guardians and welfare attorneys of living adults with incapacity have no legal power to opt them in to organ donation. The Bill does not change that position; it merely extends the principle to cover other, comparable decisions (i.e. to opt out or to appoint or withdraw a proxy).

**ECHR Implications – Article 9**

It is not reasonable to assume, as the Scottish Government appears to do, that because a person was an adherent of a particular faith, this automatically means that they must have been against organ donation. NHSBT indicate on the UK organ donation website that “The major religions in the UK support the idea of organ donation and transplantation”.

The onus is on the individual to express their belief and make their views known. An individual with a religious objection to donation can opt-out – and the Bill guarantees that a recorded objection will be respected (even if, for example, their relatives disagree).

I hope that this information will assist the Committee in its consideration of the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill.

Yours sincerely,
Anne McTaggart MSP