15 December 2015

Dear Duncan,

I am writing to provide some clarification on a couple of issues raised by the Minister for Public Health during her evidence session on 8 December 2015 and also to provide the additional information requested during my oral evidence session.

Authorised Investigating Person (AIP)

In drafting the Bill, we have assumed that existing specialist nurses for organ donation (SNODs) would be the health professionals that would carry out the tasks that the Bill assigns to the “authorised investigating person” (AIP), as they have the necessary expertise. This has been the approach taken by NHSBT in implementing the Welsh Act.

Gareth Brown, head of the health protection division in the Scottish Government directorate for population health improvement, told the Committee that the current role of specialist nurses is limited to making factual checks and providing support to families, and that they do not currently make any legal judgements (cols 12-14). He explicitly contrasted this with the Welsh Act, saying that “from memory”, it also expects NHS staff only to check facts and not to make legal judgements.

This is not the case.

In fact, the decisions that AIPs are expected to make under this Bill are very similar to those that have to be made under the Welsh opt-out system.

For example, section 5(3)(b) of the Welsh Act defines an “excepted adult” as including—

“an adult who has died and who for a significant period before dying lacked capacity to understand the notion that consent to transplantation activities can be deemed to be given”.

It then goes on to define “a significant period” as—

“a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given”.

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Clearly there are exercises of judgement (both about a person’s capacity and about what a “reasonable person” would conclude) bound up in determining whether an adult is excluded from the deemed consent provisions, and it seems inevitable that NHS staff are going to have to make those judgements, in order to establish whether the removal of organs can lawfully proceed. I do not see how the “reasonable opportunity to object” test under section 6B of my Bill would be any more difficult to apply in practice.

Another example is section 4(4) of the Welsh Act, which prevents the removal of organs from a deceased adult if “(a) a relative or friend of long standing of the deceased objects on the basis of views held by the deceased”, and “(b) a reasonable person would conclude that the relative or friend knows that the most recent view of the deceased before death on consent for transplantation activities was that the deceased was opposed to consent being given”. This, too, clearly demonstrates the need for judgements to be exercised – not just “fact-checking” as Mr Brown suggested.

A final example concerns section 8(12) of the Welsh Act, which says that—

“… if it is not reasonably practicable to communicate with [an appointed representative] within the time available if consent is to be acted upon, the person is to be treated as being not able to give consent to an activity under the appointment”.

That is the Welsh equivalent of the provisions in my Bill that require the AIP to allow “a reasonable time” for proxies to make a decision, while allowing the AIP, in deciding what is a reasonable time, to take into account “the time within which a part of the body will have to be removed if it is to be used for transplantation” (new section 6B(1)(b)(iii) and (5)(a)). Under both the Welsh Act and my Bill, these judgements will have to be made by NHS staff. In both cases, guidance to assist them in doing so should be available. The main difference is that my Bill uses a convenient label (“authorised investigating person”) to refer to the persons making these judgements, whereas the Welsh Act does not. But this is a difference in drafting approach, not in substance or practical effect.

Proxies

The Minister told the Committee that:

“If people could have up to three proxies, all three proxies would, I presume, have to be contacted and consulted before consent could be gained for the organs to be donated. That would add another complication.” (col 17)

However, the Minister’s presumption is incorrect. The Bill allows each adult to appoint up to three proxies, who must be listed in priority order. The AIP is then required to contact them in that order and to give each proxy so contacted a reasonable time to make a decision. If the first proxy can be contacted quickly, and makes a decision quickly, then there is no need to contact any other appointed proxies (see new section 6A(7) and paragraph 20 of the Explanatory Notes).
International evidence

The Minister told the Committee that:

“Scotland is up there among the countries with the highest rates of donors. I think that there are six countries that have opt-out systems and higher donor rates than Scotland and seven countries that have opt-out systems and lower rates than ours” (col 4).

This is incorrect. Nine out of 10 of the best performing countries in Europe have opt-out systems of organ donation. The UK is 12th and, if Scotland were to be included separately, it would be 15th.1 Across the world, in 2013, 10 out of the 12 best performing countries listed by IRODAT (International Registry in Organ Donation and Transplantation) had opt-out systems of organ donation and the UK was 13th.2 Scotland currently has just over half the rate of deceased organ donations that Spain has (18.2 pmp3 and 36 pmp4 respectively, 2014-15).

Deceased organ donation figures

The Minister argued that my analysis of the decrease in Scotland’s organ donation figures was unfair by suggesting this was part of a UK-wide trend, telling the Committee that: “In the past year, donor numbers have fallen slightly across the United Kingdom” (col 2).

This is inaccurate. NHSBT statistics5 show that deceased donor numbers fell in Scotland and England over the last year, but increased in Northern Ireland and Wales.

As the table below shows, deceased organ donation rates in Wales and Northern Ireland continue to increase, are static in England, and are decreasing significantly in Scotland. Scotland’s increasingly poor performance is not part of a UK-wide trend.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Scotland</td>
<td>106</td>
<td>98 (-7%)</td>
<td>41 - 16% decrease</td>
</tr>
<tr>
<td>Wales</td>
<td>54</td>
<td>60</td>
<td>31 - increase</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>46</td>
<td>48</td>
<td>27 - increase</td>
</tr>
<tr>
<td>England</td>
<td>1,114</td>
<td>1,076</td>
<td>538 – no change</td>
</tr>
</tbody>
</table>

The Minister also described my claim that Scotland’s deceased donor rate has increased by only 0.3 pmp in the last three years as “slightly misleading”, immediately afterwards saying:

“In 2007-08, our donor rate was 10.1 per million population; in 2013-14 it was 19.8 per million. Therefore, we doubled our donor rate in six years.”

There is no question that donation rates have increased since 2007, and I welcome this, but the decrease last year and even bigger decrease expected this year means that it looks increasingly unlikely that the Scottish Government will meet its target of increasing overall donation rates from 17.9 per million population in 2012-13 to 26 per million population in 2020. That, to me, indicates the limits of current approaches, and underlines the need for legislative change as part of the overall solution.

**Timeframe for a Scottish Government Bill**

The Minister was unwilling to provide a timescale for introduction of a Scottish Government opt-out organ donation Bill. If the Scottish Government’s approach is to wait and see, it should let MSPs and the public know how long that process is likely to take. To assist the Committee I have provided an estimate below of the expected timeframe, which suggests that a Government Bill – if introduced at all – would not come into effect until 2020 or 2021, between 5 and 6 years from now. Compared with what could be achieved if my Bill is passed at the end of the current session, that would be a delay of between 3 and 4 years.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tr>
<td>Welsh Government evaluation (2 years)</td>
<td>late 2017⁶</td>
</tr>
<tr>
<td>Scottish Government’s evaluation (3 months)</td>
<td>early 2018</td>
</tr>
<tr>
<td>Scottish Government consultation (6 months minimum)</td>
<td>late 2018</td>
</tr>
<tr>
<td>Introducing a Bill and parliamentary scrutiny (1 year)</td>
<td>late 2019</td>
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<tr>
<td>Publicity campaign ahead of the Bill’s implementation (1-2 years)</td>
<td>late 2020/21</td>
</tr>
</tbody>
</table>

**Possible stage 2 amendments**

Committee members asked me about the type of Stage 2 amendments that could be considered. The purpose of the Bill is to establish a soft opt-out system of organ donation in Scotland. Therefore any amendment that would change the purpose of the Bill would be inadmissible. However, the provisions in the Bill which have been included to implement a soft opt-out system could be amended.

My intention is for the Scottish Parliament to pass the best piece of legislation possible, so that this Parliament can introduce a soft opt-out system of organ donation. As I have already indicated I would be happy to consider amendments to reduce the number of proxies from three to two, and to increase the minimum period of residency from 6

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months to (say) 12 months. I have also accepted that the designation of the AIP should be drawn more narrowly so that it can only apply to NHS health professionals. I look forward to the Committee’s stage 1 report and if there are other changes that committee members feel would improve the Bill then I would be more than happy to consider them.

50 years of international evidence

Nanette Milne asked (col 37) what basis I had for referring to “over 50 years of international evidence”. Opt-out systems of organ donation have been legislated for since 1953, when Israel introduced the Anatomy and Pathology Law. International evidence has analysed the impact of opt-out organ donation systems since that time.

I hope that this further information will assist the Committee in its consideration of the general principles of the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill. If I can be of any further assistance please let me know.

Yours sincerely,

Anne McTaggart MSP