Transplantation (Authorisation of Removal of Organs etc.) Scotland Bill

Scottish Government

Introduction

1. This memorandum has been prepared by the Scottish Government to assist consideration by the Health and Sport Committee of the Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill, which was introduced by Anne McTaggart MSP on 1 June 2015. This paper is necessarily long given the importance and complexity of the legislation, the sensitivity of organ donation as an issue, and the number of concerns the Scottish Government has in relation to this particular Bill. One such concern is the extent to which the measures contained within the draft Bill may have been tested with experts working in the field of organ donation. Whilst this paper has been informed by our work with stakeholders, it is a Scottish Government view. We would strongly recommend actively seeking information and evidence from the key expert organisations and individuals working in this complex area.

Summary of Scottish Government View on the Bill

2. The Scottish Government commends the aim of the Bill, but is not in a position to support it. The reasons for this, which are set out in detail within this paper, are across three main areas:

2.1. Whilst we are not close-minded to introducing a presumed consent with opt-out system in Scotland, we would only do so if convinced that there is evidence that such a change would be effective. Currently, we are not convinced that the Bill would lead to an increase in the number of organs and tissues being made available for transplant, because:

(i) there is still a lack of clear-cut evidence that presumed consent with opt out would result in any increase in organ donor rates or organ transplants;

(ii) introducing a legal provision to ‘opt out’ of organ donation is unnecessary as this option is already provided via the existing NHS Organ Donor Register. Additionally, opting-out has the potential to reduce the opportunities to assess whether someone may have changed their mind about organ donation during their life-time, and may unintentionally lead to instances where organ donation could have gone ahead, but did not.

(iii) the introduction of presumed consent (‘authorisation by operation of the law’), as set out in the Bill and its accompanying documentation, does not adequately address the needs of those who may wish to opt out, but who do not do so, for whatever reason. This may result in distress to families, or to complaints or legal challenges at European level.
2.2. We have significant concerns about specific measures set out in the Bill and its Policy Memorandum, specifically:

(i) Proxies - At its best, the introduction of optional proxies will add a potentially time-consuming layer of administration to the current time-critical organ donation processes. At its worst it has the potential to result in significant additional distress to the families, the proxies and to clinical staff.

(ii) Authorised Investigating Person - The Bill views the role of Authorised Investigating Person as integral to the efficient working of the new system. Our view, however, is that the additional checks required, and their legal complexities, would be more likely to slow the system down. Additionally, if it is possible to set aside the requirement for AIPs to investigate and authorise 'lawfulness', then current role of SNODS and surgeons suggests the AIP role is not necessary.

(iii) Legal Implications - Unless addressed, there are specific legal concerns in respect of adults with incapacity, who may, under the Bill as currently worded, become 'locked in' to organ donation. There are also concerns as to whether the priority given to proxy decisions, and presumed consent itself, could be seen as contravening Article 8 or Article 9 of ECHR law.

2.3 We have concerns that the financial cost to Scottish Ministers and the NHS of introducing and maintaining the Bill’s measures have not been fully reflected.

(i) In our view the Bill’s Financial Memorandum significantly underestimates the potential costs of the legislation to Scottish Ministers – a difference of approximately £16 million over 10 years.

(ii) There is also a lack of clarity on the potential costs to the NHS as a result of there being no estimate provided on the potential increase in donors and transplants which the legislation would be expected to provide.

(iii) Whilst high or unknown costs are not, in themselves, a barrier to implementing any measures which would improve or save lives, they are significant in the context that there is no certainty that this Bill will achieve its aim, and no information provided on the number of additional donors to which it is expected the legislation would lead.

Background
Recent Achievements
3. Since the recommendations of the UK Organ Donation Taskforce in 2008\(^1\), the UK has seen significant improvement in its organ donation rates

\(^1\) http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf
and statistics, and figures are now much more comparable with rates elsewhere in Europe.

4. Whereas in Scotland in 2007/8 the number of deceased donors was 54, the latest 2014/15 number is 98, an increase of 82% that is well ahead of the target 50% increase over five years set by the Organ Donation Taskforce. This success is largely down to the successful implementation of the Task Force’s key recommendations, which were augmented by the Scotland-specific strategy SG publication ‘A Donation and Transplantation Plan for Scotland 2013 – 2020’.

5. Of all the UK administrations, Scotland also currently has the highest percentage of its population on the Organ Donation Register, at 41%. Anyone from age 12 years can register, as determined by the Human Tissue (Scotland) Act 2006.

6. In Scotland in 2014/15, there were:

- 98 deceased donors and 81 living donors.
- 300 deceased donor transplants and 78 living donor transplants.
- 543 people on the active transplant waiting list at the end of the year, a reduction of 21% from 2007/8.

7. The types of transplants which make up these figures are: kidney, kidney/pancreas, pancreas islets, heart, lung(s), liver/lobe, intestinal and other (multi-organ). The majority are either kidney or liver/lobe transplants.

8. Organs from a Scottish donor can be used for transplantation anywhere in the UK, and vice versa. For this reason, there is no direct correlation between the number of organ donors in Scotland and the number of transplants in Scotland.

9. The organ donation decisions made by families are supported by a network of 18 WTE Specialist Nurses in Organ Donation, working in and across 24 Scottish hospitals and operationally managed by the UK wide NHS Blood & Transplant. Scotland’s organ retrieval service is based in Edinburgh, with input from the cardio-thoracic team at Glasgow’s Golden Jubilee National Hospital.

The Scottish Government’s Pre-existing View on ‘Opt-out’


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3 [https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf](https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf)
11. The Bill Policy Memorandum states at paragraph 33 that the Government’s strategy ‘makes no reference to a move to an opt-out system.’ This is incorrect. The report was informed by the key organ donation stakeholders to Scottish Ministers, the Scottish Transplant Group (now called the ‘Scottish Donation and Transplant Group’) and its second recommendation at Annex A, page 24 is as follows:

“Members of the Scottish Transplant Group have previously provided views on the potential benefits of the introduction of an ‘opt-out’ system of consent within Scotland. There is no consensus amongst members of the STG as to whether or not ‘opt-out’ would increase donation rates in Scotland. Given this, and the fact that significant improvements have been achieved over the last five years in relation to donation and transplantation rates in Scotland, the Scottish Government should await evaluation of the move to ‘opt-out’ in Wales before making any decision about the introduction of opt-out in Scotland.4”

Discussion

12. The remainder of this paper provides further narrative on a number of specific aspects of the proposed Bill, as follows:

1. Whether the Bill will lead to an increase in donor/transplant numbers
2. Opting Out
3. Presumed Consent/’Authorisation by Operation of the Law’
4. Proxies
5. Authorised Investigating Person
6. Requirements on Scottish Ministers
7. Legal Implications
8. Financial Implications
9. Consultation

13. The Annex to this submission comprises the factual paper recently provided to the Finance Committee on the financial implications of this Bill.

1. Will Organ Donor and/or Transplant Numbers increase as a result of this Bill?

14. The Bill’s Policy Memorandum states at paragraph 4 that ‘The overall aim of the Bill is to increase the number of organs and tissue made available for transplantation in Scotland, and hence to allow more transplants to be carried out, reducing waiting lists and saving lives.’

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15. This aim is commendable, however it incorporates the implicit assumption that a presumed consent with opt-out system will lead to an increase in organs in the first place, which we do not believe to be necessarily the case.

The Appeal of Opt-Out

16. Changing to an ‘opt-out’ organ donation system in Scotland is a topic which arises frequently and which has a great deal of support from the general public. In simple terms, a shortage of donor organs suggests moving to a default position where everyone is presumed to want to be a donor, unless they explicitly opt out. It is not, however, true to say that more potential donors will necessarily lead to more actual donors. The organ donation pathway is complex, and there are many different issues which can influence whether or not an individual becomes a donor and, thereafter, whether those donated organs can be used. This means that it is not at all clear that an opt-out system would be beneficial. The rate-limiting step for organ donation is, in fact, the number of people who die in circumstances where donation is possible. The legislation would do nothing to change that.

17. There is also another UK factor that needs to be borne in mind. Although practice and systems have improved, and we now have the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, we are not too many years away from the cases of organ retention without consent at Alder Hey Hospital in Liverpool and (to a lesser but still serious extent) Yorkhill Hospital in Glasgow. There will be many who still remember or who are still affected by what happened, and who may rightly have doubts as to whether moving to a presumed consent system would be the right way forward.

Evidence from Other Countries

18. The Bill’s Policy Memorandum cites evidence from other countries who have moved to an opt-out system and whose organ donor rates are higher than the UK, or Scotland. In doing so, it compares - at paragraph 20 - the 2007/8 UK organ donor rate of 12.9 per million population (pmp) with France at 23.2 pmp and Italy at 21.7 pmp. Paragraph 24 cites a further seven countries with opt-out systems, whose organ donor rate pmp is higher than the UK was in 2007/8. It should be stressed, however, 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.

19. The most notable exception is that of Spain, which has an opt-out system and an extremely high organ donation rate of 35.5 pmp. Whilst this initially appears to be compelling evidence in support of opt-out, it should be noted that Spain did not experience an increase in its organ donation rates until ten years after its opt-out legislation was introduced. Nor was this the only change introduced. Much of Spain’s rate increase is attributed, not to opt-out, but to improvements in its donation and transplantation infrastructure and
public awareness-raising\textsuperscript{5}. This attribution extends to the architect of this revised Spanish organ donation system, Rafael Matesanz, who wrote in a Guardian opinion piece that support for presumed consent was “very curious, given the weakness of the evidence supporting presumed consent as a significant factor in organ donation. In our view, it contributes little or nothing to the improvement of organ donation rates and, on the debit side, diverts precious resources to imaginary rather than effective solutions”\textsuperscript{6}. Many of the practical changes he introduced in Spain were explicitly recognised and recommended by the previously mentioned UK Organ Donation Taskforce in its report. The successful implementation of these measures in Scotland (and in the UK) has undoubtedly helped to result in the 82% increase in deceased organ donor numbers in Scotland since 2007/8.

20. The deliberations of the Welsh Government, which will implement its new opt-out system in December of this year, were informed by its commissioned social research paper\textsuperscript{7} that sought to update a key 2008 piece of comparative research from the University of York, and which itself utilised research studies from 2005, 2006 and 2007. The social researchers' overall conclusion was that ‘Although six methodologically robust studies have found that opt-out systems for organ donation are associated with increased organ donation rates and increased reported willingness to donate, it cannot be inferred that this association means that presumed consent causes increased organ donation.’ And that, although Welsh public support for opt-out was a further, positive factor ‘there can be no guarantees that this legislative change will result in increased organ donation rates.’

21. A more recent interesting research panel paper, authored by Shepherd, O’Carroll and Ferguson and published by the British Medical Council in 2014\textsuperscript{8}, sought to fine-tune the pre-existing research and found that, whilst opt-out might increase deceased organ donor rates, it might also reduce living donor rates. Overall, whilst the evidence tends to suggest that opt-out may have some kind of positive impact on organ donor rates, it is as yet far from conclusive.

22. The Welsh Government based its decision to go ahead with its new opt-out legislation on a favourable interpretation of the available evidence (plus other Wales-specific factors). This was their choice to make and they may be proven right. The Scottish Government view, however, continues to be that the available evidence in support of opt-out is not sufficiently clear-cut to suggest a move to a system of presumed consent with opt-out in Scotland, at this time.

Calculating Increases to the Donation and Transplant Rates

23. A significant omission from the Bill’s Policy Memorandum and Financial Memorandum is any indication of how many extra organ donors or transplants

\textsuperscript{5}http://onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.2003.tb00233.x/abstract;jsessionid=9E43165545BCAB5051F56B10A37C4353.f01t04
\textsuperscript{6}http://www.theguardian.com/commentisfree/2008/nov/17/organ-donation-health
\textsuperscript{7}http://gov.wales/docs/caecd/research/121203optoutorgandonationen.pdf
\textsuperscript{8}http://www.biomedcentral.com/1741-7015/12/131
will, or even might, result from its proposed measures. As a result it is impossible to calculate what the actual cost to the NHS in Scotland may be if the Bill becomes law.

24. Given the lack of clarity on this point, we asked NHSBT to provide us an estimate for Scotland which utilised the same methodology taken for calculating the Welsh estimated increase. This provided a range of possible outcomes, with their preferred most reasonable estimate being that, under a presumed consent with opt-out system in Scotland, there might be up to 39 additional organ donors in Scotland, or circa 120 organ transplants which might be available for recipients UK wide. Given the population ratios across the UK, this estimate suggests there might be approximately 12 additional organs available for transplant into Scottish recipients.

25. In order to make the calculations, and reach this estimated number, NHSBT had to make some initial assumptions. One assumption was that the conversion rate from authorisation to actual donation would remain the same i.e. that the same % of transplants would go ahead once recipient health, availability, organ compatibility etc. factors were taken into account. However, there may well be unexplored bottlenecks e.g. finite facilities and resources in hospitals that mean the conversion rate is more ‘fixed’ than the calculations assumed. In this scenario, any increase in authorised donors might come up against the wall of finite resources and facilities and the conversion rate would therefore drop, reducing or negating any increase in actual donation.

26. Another key assumption was that next of kin would be more likely to authorise donation in hospital under a presumed consent system, an assumption based on evidence from other countries. As previously set out, however, the evidence from other countries is open to different interpretations.

27. In short, in order to calculate what any increase in donor and transplant rates might be under a presumed consent with opt-out system, it is necessary to first assume that there will be an increase and also that hospitals are already fully set up to deal with any increase. In our view, the available evidence is not sufficiently clear-cut on the first assumption, and the second assumption is untested. Therefore the NHSBT estimated increase of 12 additional organs for Scottish transplant recipients, or any organ donation increase at all, is by no means certain.

**Conclusion**

28. Our view is that, given that there is still a lack of clear-cut evidence that presumed consent with opt out would result in any increase in organ donor rates or organ transplants, the Scottish Government should continue to await evaluation of the move to opt-out in Wales before making any decision about the introduction of opt-out in Scotland.

2. **Opting Out**

**Registering an Objection to Organ Donation**

29. Section 1 of the Bill 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 to the removal and use of a part of their body after death for transplantation. Essentially, this provides the legislative basis for an adult to record a wish not to donate.

30. It is not clear that this provision is needed. Section 6 of the Human Tissue (Scotland) Act 2006 already provides that an adult may withdraw authorisation for the removal and use of a part of their body after death for various purposes. Although not explicitly articulated as providing an adult with a legal basis to register an objection to donation, the effect is the same. The adult can, in writing, withdraw their authorisation for donation. This does not require a positive authorisation to have been given previously.

31. Furthermore, in practice, under the new NHS Organ Donor Register introduced across the UK in July 2015, any adult in Scotland can already register their objection to donation under current legislation. The registered wish, whether to opt in or out, would be respected by the NHS should that person die in circumstances where donation could proceed. The proposed provision therefore appears unnecessary.

**Sixteen Years and Over**

32. It is also not clear why the provision as drafted applies only to adults, which the Policy Memorandum more explicitly notes as those aged 16 years or over.

33. Even though the ‘authorisation by operation of law’ (i.e. the presumed consent) would only apply to adults, there seems no reason why children aged 12 or above should not register their objection to donation by opting-out, in the same way as they can currently opt-in. In fact, children of twelve and over can already opt-out via the July 2015 revised Organ Donation Register, therefore the Bill risks removing a right that children currently have. Again, the legal basis for this is already set out within the Human Tissue (Scotland) Act 2006. Allowing children of twelve years and over the choice of explicitly opting-in or opting-out would provide parents or nearest relatives with a clear expression of the child’s wishes.

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

34. The Bill does not fully address the scenario where the deceased may have changed their opinion on organ donation during their life-time, but has not updated their entry on the organ donor register to reflect this change. Whilst paragraph 48 of the Policy Memorandum includes an option to check whether someone has recently changed to an opt-out position, it does not make any reference to the opposite scenario where someone has changed to an opt-in position.

35. Under the current (and still nearly entirely) opt-in system, a Specialist Nurse in Organ Donation will check the Register and if the deceased has opted-in or not registered at all, then they will raise the topic of organ donation with the next of kin, which automatically allows for an assessment of the deceased’s most recently expressed wishes.
36. By contrast, under a system where an opt-out decision by the deceased is upheld by law, no approach could be made to the next of kin to find out if the deceased had subsequently changed their mind and had been in favour of organ donation before they died. And even if the next of kin, unprompted, advised that the deceased had recently changed their mind to being in favour of organ donation, it is unclear whether any donation could legally proceed. As such, an unforeseen consequence of this might be an actual reduction in organ donations. A potential added complexity is the role and legal status of the proxy, which is set out later in this paper.

Not ‘Getting Around’ to Registering

37. Paragraph 21 of the Policy Memorandum notes that ‘A YouGov survey in 2007 indicated that 74% of respondents in Scotland supported a system of presumed consent for organ donation, whilst a Scottish Government survey undertaken in 2012 found that only 5% of the population opposed organ donation in principle.’

38. We do not dispute, and we welcome, this widespread support for organ donation in Scotland. It is significant, however, that despite this support, the percentage of eligible donors in Scotland signed up on the register is 41%. This is a high percentage for any country, yet it strongly suggests that whilst the majority may support donation, a significant number of that majority simply do not ‘get around’ to registering, despite on-going, high-profile media campaigns.

39. By extension, it seems logical to think that under an opt-out system, not everyone who wants to opt-out – however well-informed they may be – will actually ‘get around’ to opting out. The Bill proposes a number of checks and safeguards to help determine whether a donation can go ahead in the absence of an opt-out instruction, however there is still potential for significant subsequent distress to next of kin who may not have been contactable at the decision point and (as a result) there is potential for complaints about, or legal challenges to, the decisions made by any or all of the medical staff and specialists involved in those decisions.

Conclusion

40. Introducing a legal provision to ‘opt out’ of organ donation is already an option via the existing organ donation register and is therefore unnecessary. Additionally, opting-out has the potential to reduce the opportunities to assess whether someone may have changed their mind about organ donation during their life-time, and may unintentionally lead to instances where organ donation could have gone ahead, but did not.

3. Presumed Consent / ‘Authorisation by the Operation of Law’

41. Section 6 of the Bill, and paragraphs 44 to 48 of the Policy Memorandum, articulates the policy aim of presumed consent through the concept of ‘authorisation by operation of law’. Essentially, if no wishes in respect of organ donation have been registered or are known to next-of-kin or
‘proxies’ then, assuming certain pre-conditions are met, authorisation is considered granted and organs can be removed for the purposes of transplantation. It is possible that European Court of Human Rights Articles and case law may have a bearing on this. Detail on this is set out in the ‘Legal Implications’ section of this paper.

Presumed Consent After Six Months Habitual Residency

42. The Bill’s Policy Memorandum assertion, at paragraph 47, is that it is reasonable to assume that an adult who has an objection to donation would opt out within a period of six months of habitual residency in Scotland. This appears to be a subjective judgement, and Parliament would need to take a view on this. It is not difficult, however, to envisage situations where, as noted earlier, an individual simply does not ‘get around’ to opting out, or that they have not picked up on awareness raising or communications. The six month residency can be expected to have additional implications and significance for international students, foreign contractors and new permanent residents in Scotland (and, of course, their next of kin), particularly if English is not their first language and/or their culture or religion does not allow for organ donation.

Adults with Incapacity

43. As set out above, it is likely that there are some who will not opt out regardless of how long they have been resident in Scotland. This would also be the case for adults who are permanent residents in Scotland but who are classed as ‘adults with incapacity’ as defined within the Adults with Incapacity (Scotland) Act 2000. The complexities are set out later within the ‘Legal Implications’ section of this paper, however the concern, in brief, is that adults with incapacity could end up being ‘locked-in’ to organ donation as neither they, nor someone acting on their behalf under the provisions of the 2000 Act, would be able to appoint a proxy, or be able to register an objection to the removal of organs.

Rebuttable Presumption

44. Paragraph 47 of the Policy Memorandum sets out where, if any applicable information comes to light that indicates the deceased did not have a reasonable opportunity to opt out, then an ‘Authorised Investigating Person’ or ‘AIP’ can rebut the presumption of consent, and the donation would not proceed. There is no clear suggestion, however, as to what that applicable information might be, other than ‘this might, for example, be because they were not present in Scotland for most of that time [i.e. six months] or lacked capacity for a significant part of it’. This will require to be clarified generally for the purposes of initial consideration of the Bill but also for reasons of legality, given the role of the AIP (discussed in detail below) is to determine the ‘lawfulness’ of organ donation.

Conclusion

45. Our view on the introduction of authorisation by operation of the law, as set out in the Bill and its accompanying documentation, is that it does not
adequately address the needs of those who may wish to opt out, but who do
not do so, for whatever reason. This may result in distress to families,
complaints to the NHS and/ or legal challenges at European level.

4. Proxies

46. Sections 4 and 5 of the Bill, and paragraphs 49 and 50 of the Policy
Memorandum, propose that adults will be able to appoint proxies to make
decisions, after that adult’s death, to authorise the removal of organs for
transplantation.

47. This is described as ‘an additional positive choice for an adult’, and is
described as an alternative to either opting in or opting out. To be valid, proxy
details can be included within the organ donation register or can pre-exist in
writing, signed by the deceased, and should contain accurate contact
information.

Proxy Precedence Over Next of Kin

48. At present, under the Human Tissue (Scotland) Act 2006, the nearest
relative can authorise donation on behalf of a deceased person if that person
has not expressed a wish to donate in life.

49. By contrast, paragraph 46 and 54 of the Policy Memorandum, and the
order of Section 6 of the Bill, makes clear that the intention is for the existence
of a proxy to be determined, and their authorisation sought, before the views
of next of kin are sought. More than that, the effect would be that the proxy’s
views would legally over-rule the views of next-of-kin as expressed in
paragraph 54 ‘Section 7 of the 2006 Act allows authorisation to be given by a
nearest relative…The Bill does not repeal this provision, although it is
amended to ensure it cannot be exercised while the question of proxy
authorisation is under active consideration’.

50. The reason for this is unclear within the Policy Memorandum. Paragraph 50 states that ‘the general aim… is to secure a decisive answer to
the question of authorisation as quickly as is consistent with giving the
individuals involved a reasonable time to make difficult decisions’, which is no
different from the current system and aim of contacting next of kin. Paragraph
53 sets out the difficulties involved in having to seek authorisation from a list
of relatives in the right order, but makes no explicit statement that the role of
the proxy is, e.g., to save time by bypassing this list, nor does this seem likely
given that up to three proxies are allowed under the Bill. Paragraph 54 of the
Policy Memorandum appears to take the more compassionate, if arguably
paternalistic, view that proxy authorisation will help ‘avoid the emotional
burden that asking relatives directly to authorise organ removal can often
place on them’. It may also be that this proposal is seeking to avoid the
situation where relatives disagree on the deceased’s wishes, or where a
relative over-rules the deceased’s known wish to donate after death.

51. The fact that the Bill appears to give decision-making priority to a proxy
over the next of kin is a significant measure that Parliament should be
explicitly and clearly sighted on, along with clearly stated reasons as to why it is deemed necessary. This issue also raises some implications in relation to Article 8 of the European Court of Human Rights, which are set out in the ‘Legal Implications’ later section, and of which Parliament should be aware.

52. We would also raise questions about who a proxy could be. It is not clear from the Policy Memorandum if a proxy could also be a family member or not, or if a proxy could be a health professional or a GP. This might give rise to difficult regulatory issues about the role of health care workers. In introducing the concept of a proxy there should be a clear understanding of what sort of individuals could, or could not, be proxies.

Will Proxies Work, in Practice?

53. Even if proxies are given decision-making precedence, it is not clear that this will actually work in practice, given that in most instances only nearest relatives would be able to discuss and provide the information necessary to satisfy the clinical requirements on whether donation can proceed.

54. It is very difficult for donation to proceed without detailed information about a donor’s personal health, family medical history, lifestyle and so on. This is vitally important to ensure that the transplanted organs are safe and will do no harm to the recipient. This is not an abstract risk - recent high profile cases tell of transplant recipients dying or contracting cancer as a result of receiving unsafe organs. In practice, therefore, the nearest family member has significant power over donation whether or not there is a separate mechanism to legally authorise donation.

55. In the situation where all the clinical requirements are met and the proxy has made a decision (whether to proceed or not to proceed with donation) that conflicts with that of the family, it is easy to envisage how difficult and distressing that situation will be for clinicians to manage, regardless of what the law says. It is unlikely that clinicians would act against the wishes of nearest relatives even if there is a legal basis for doing so.

56. This reality is borne out by the fact that the law in Scotland already does not allow families to over-rule a deceased’s decision to donate, and yet in practice clinicians will not proceed with donation if the family does not support the process, even if the deceased had clearly expressed a wish to donate. Where the law has not worked before, it is unlikely that a new law introducing an additional layer of complexity will work.

57. We note that much later at paragraph 64 of the Policy Memorandum, under the separate ‘Alternative Approaches’ section, there is a statement not found anywhere else, saying that introducing proxies ‘is not an essential feature of a soft opt-out system’. We strongly agree with this assessment.

Conclusion

58. At its best, the introduction of optional proxies will potentially add a time-consuming layer of administration to the current time-critical organ
donation processes. At its worst it has the potential to result in significant additional distress to the families, the proxies and to clinical staff.

5. **Authorised Investigating Persons (AIP)**

59. Section 2 of the Bill and paragraphs 41, 46 to 50, 53 and 55 of the Policy Memorandum introduce and explain a new role of ‘Authorised Investigating Person’ (AIP). In the Scottish Government’s paper to the Finance Committee, we erroneously stated that the Policy Memorandum notes this role as being ‘optional’. In fact it was the role of proxy (above) which was optional. The role of AIP along with its associated costs is, in fact, an integral element of the Bill.

### The Role of the AIP

60. The role of the AIP will be to check that the deceased has either opted in or opted out; whether or not they had appointed a proxy, and if any such proxy is available and able to make a decision at the point of donation. In the event that there is no proxy appointed, then a series of further checks will be made with the nearest relatives, including whether the deceased person had no reasonable opportunity to opt out in the previous six months. If any applicable information comes to light that indicates the deceased did not have a reasonable opportunity to opt out, then the draft legislation allows the AIP to stop a donation from proceeding. The role is described as one which would be undertaken by ‘health professionals’, but with no further elaboration. Instead the Bill allows for the detail of who will undertake the role to be set out in Regulations, rather than in the Act itself.

### Practical Impact of Checks by the AIP

61. Given the ultimate aim of the Bill is to increase the number of donors, the practical impact of these authorisation checks will need to be considered. There is nothing within them that would reduce the current administrative burden associated with organ donation; instead it will introduce an additional set of checks that would need to be undertaken if the deceased person had a proxy (or, indeed, multiple proxies). It introduces additional complexities to the existing pathway, even potentially including additional professionals in the form of AIPs, if the role cannot be accommodated within existing staff roles. The reality is that this will slow down the donation process as the NHS will have to go through the various additional checks and determinations before organs can be donated.

62. We are already aware that potential donors are lost because of the time it takes to process authorisation – families often do not want to wait 12 or 24 hours after the death of a loved one for organs to be donated, and indeed the longer it takes to retrieve organs the less viable many of those organs will be. There is a real risk that introducing the additional authorisation checks set out in the Bill will result in slowing down the process even further for all donors, and actually reduce the number of useable organs being transplanted.
63. What initially seems a minor lack of clarity over the role title actually has some significant implications. Is an ‘authorised investigating person’ someone who is authorised to investigate or someone who investigates in order to authorise? It is unclear from the role title where they would stand in the decision-making hierarchy. This makes it difficult to assess how the proposals would work in practice and also difficult to assess a professional grade and salary band. Given the role is, as previously noted, an integral part of the proposed new system, this issue requires to be clarified.

64. Paragraph 41 of the Policy Memorandum states that the AIP role is ‘to determine whether or not a deceased adult's organs can lawfully be removed and used for transplantation’. Also that it is the role of the AIP ‘to consult the nearest relative to determine whether they are aware of any objection…’. These statements tend to suggest an investigative role, however later in paragraph 45 it is stated that ‘it is the job of the… AIP to investigate and reach a conclusion’, which is moving more towards an authorising role, although it is still unclear. Finally, at paragraph 55, the following is set out ‘The AIP’s role, in particular, is to state a conclusion under new section 6B [i.e. the lawfulness of removing organs for transplantation] taking into account information provided by the deceased person’s nearest relative. But it is important to note that having lawful authority to remove an organ, for example, does not mean it will be removed. The person responsible for the removal must still decide that the organ is suitable.’

65. Our reading of this suggests that whilst the final say belongs to the surgeon (ie ‘the person responsible for the removal’), this is only on clinical grounds. The AIP is the one both investigating and making the final decision on whether organs can legally be removed.

66. The Bill is therefore effectively proposing that one health professional will determine the lawfulness of organ donation. It is not clear to what extent this issue has been tested with the NHS or with the practitioners who might be called upon to make such judgements. Medical professionals may not be personally willing, or professionally able, to make such legal decisions.

67. For example, the most obvious candidate to take on this type of additional role is that of the Specialist in Organ Donation (SNOD). At present, a cadre of 18 WTE SNODS work across Scotland, and are responsible for supporting the donation process e.g. working with families, checking the NHS Organ Donor Register, determining whether a wish to donate has been expressed or otherwise, discussing donation with families and seeking authorisation or not as appropriate for donation.

68. SNODs are not explicitly named or defined within current legislation, and are not legally responsible for decisions about whether or not to proceed with donation or not. Their role is to gather factual information (e.g. is the individual on the register) and support decision-making by the family and then by the medical practitioner responsible for the retrieval of organs – usually the
surgeon. They therefore largely undertake the role of ‘investigator’ rather than that of ‘authoriser’.

69. Complicating the role of the SNOD to include responsibility for determining the lawfulness of donation would almost certainly be a step too far, and may also present a conflict of interest in that a SNOD would be both investigating and authorising lawfulness. Instead, it is likely that there would be a need for the development and establishment of a new specialist team of AIPs, with all the additional costs and requirements associated with that. These were set out in our paper to the Finance Committee and are also referenced within the ‘Financial Implications’ section of this paper.

70. However, it is important to note that under Section 11(4) of the Human Tissue (Scotland) Act 2006, it is the medical practitioner who will be carrying out the removal of organs who is currently responsible for ensuring that the donation has been authorised in line with the Act. It also has to be acknowledged that even if the legislation was introduced as drafted, the ultimate decision about whether or not to proceed to donation would still remain, on clinical grounds, with the medical practitioner who would carry out the retrieval of the organs.

71. If retrieval surgeons are not supportive of the proposed principles, or have any doubts about any particular case in practice, donation would not proceed regardless of the conclusions of the AIP and it is likely that a high-threshold of doubt would be applied to any case given the sensitivities around organ donation. The surgeon is already, and would be likely to remain, the ‘authoriser’ rather than the ‘investigator’.

Conclusion

72. The Bill views the role of Authorised Investigating Person as integral to the efficient working of the new system. Our view, however, is that the additional checks required, and their legal complexities, would be more likely to slow the system down. Additionally, if it is possible to set aside the requirement for AIPs to investigate and authorise 'lawfulness', then the current role of SNODs and surgeons suggests the AIP role is not necessary.

6. Requirements on Scottish Ministers

Opt Out Register

73. There are no particular difficulties with the requirements on Scottish Ministers, other than costs. The main requirement for Scottish Ministers is to approve a register for individuals to register their 'opt out'. As already set out, such a register already exists – the NHS Organ Donor Register. This was revised to support the Welsh opt out which comes into effect in December 2015, and which has been available since July 2015. This enables all UK (including Scottish) residents to register objections to organ donation under current legislation. This means that in the future, those who do not wish to donate (as well as those who do) will be clear from the initial check of the Organ Donation Register as part of the end-of-life care process.
Awareness Raising

74. The other absolute requirement for Scottish Ministers is to raise awareness about the introduction of soft opt out over a period of six months prior to the legislation being introduced. The campaign suggested by the Bill and its accompanying documentation is most notable for its six month duration, which we believe to be entirely insufficient, and its estimated costs of £2.8 million over one year.

75. Our own estimate, based on a revised model that has been informed by previous organ donation campaigns and also by our Welsh counterparts, is a roughly comparable £3.3 million over either one or two years, depending on the implementation schedule of the Bill.

76. An additional requirement, however, which is not mentioned within the Bill documents, is the need for an on-going awareness-raising campaign after implementation. Full details are contained within our paper to the Finance Committee, which is attached as an Annex.

Conclusion

77. Other than costs, there are no significant issues in respect of requirements on Scottish Ministers.

7. Legal Implications

Adults with Incapacity under a Presumed Consent System

78. Section 6 of the Bill proposes to amend the Human Tissue (Scotland) Act 2006 to insert a new section 6B, which would permit the removal of organs for transplantation 'by operation of law' (i.e. presumed consent), provided that certain criteria are satisfied.

79. The question of whether adults with incapacity can self-authorise organ donation, or have someone authorise this on their behalf, is not addressed within the Adults with Incapacity (Scotland) Act 2000. The current legislation in this area that would allow organ donation to proceed in these circumstances is provided under Section 7 of the Human Tissue (Scotland) Act 2006, for the next of kin to authorise organ donation.

80. However, Section 15 of the Bill amends the Adults with Incapacity (Scotland) Act 2000 ("the 2000 Act") to state that the powers conferred on a welfare power of attorney (under section 16 of the 2000 Act) or a guardian (under section 64 of the 2000 Act) does not include the power to make or withdraw the appointment of a proxy, or include the right to record an objection to the removal of the adult's organs. The Scottish Government is concerned that this could leave the next of kin/guardian unable to exercise their current right (under Section 7 of the 2006 Act) to not allow a donation to proceed.

81. Section 6B, as proposed, provides for presumed consent where there has been no direct authorisation; no recorded objection; no decision made by
an appointed proxy; and the nearest relative has no actual knowledge that the adult was unwilling for organ removal for transplantation. The Scottish Government is concerned that as drafted, the bill would leave adults with incapacity being essentially ‘locked-in’ to the organ donation as they, or someone acting on their behalf under the provisions of the 2000 Act, will neither be able to appoint a proxy, nor to register an objection to the removal of organs.

82. Our view is that this provision may have the undesired effect of making it difficult for adults with incapacity, and their next of kin/guardians, to opt-out of the provisions relating to the authorisation of the removal of organs by operation of law.

ECHR Implications – Article 8

83. Article 8(1) of the European Convention on Human Rights provides that ‘everyone has the right to respect for his private and family life, his home and correspondence’. Case law from the European Court of Human Rights has long recognised that the circumstances in which Article 8(1) may be engaged are broad and not susceptible to exhaustive definition.

84. The changes proposed by section 8 of the Bill will have the effect of providing that the nearest relative of a deceased may not make an authorisation under section 7 of the 2006 Act if a proxy has been appointed and is known to be either in the process of making a decision on removal for transplantation, or has decided against such removal. The Scottish Government is concerned that in circumstances where a proxy seeks to over-rule the wishes of a bereaved family member, it is possible that the provisions of the Bill may engage the Convention Rights of the family of a deceased person, whose organs are removed for transplantation under the Bill contrary to their wishes. These concerns would obviously need to be addressed.

ECHR Implications – Article 9

85. The Scottish Government is mindful that there is central belief within some religions that a human body must remain whole even after death, and as such organ removal for transplantation may offend the religious beliefs of the deceased, or their relatives. Whilst the ability to record an objection (section 6 of the 2006 Act and section 1(1)(b) of the Bill) would provide an opportunity for objection based on religion, the previously stated concerns with Section 6B potentially ‘locking in’ some individuals to organ donation, may become particularly relevant here.

86. More generally, whilst informal objections based on religion may be made by the deceased during their life, and may constitute “actual knowledge that the adult was unwilling for the part to be removed and used for transplantation” (section 6B(1)(vi) as proposed by section 1 of the Bill), it is possible that inferring an objection from the fact of the deceased being of a particular religion would not in itself constitute ‘actual knowledge’ and consequently, organ removal for transplantation could be authorised by operation of law provided the other criterions are satisfied.
87. Article 9(1) of the European Convention of Human Rights enshrines the right of the individual to hold, change and manifest philosophical or religious beliefs, either alone or in common with others. The Scottish Government is concerned that further consideration should be given to whether the Article 9 rights of the deceased’s family will be engaged by the provisions of the Bill.

Conclusion

88. There are specific legal concerns with the current drafting of the Bill, which may give rise to adults with incapacity and their next of kin/guardians being ‘locked in’ to organ donation. There are also concerns as to whether the priority given to proxy decisions, and presumed consent itself, could in certain circumstances be seen as engaging or contravening Articles 8 and 9 of ECHR law.

8. Financial Implications

Costs to Scottish Ministers

89. While the Financial Memorandum suggests costs to Scottish Ministers might be in the region of £6.1 million over 10 years, our own calculations suggest that implementing the Bill as drafted would have a cost closer to £22.2 million over ten years, and with recurring costs of circa £2 million each year thereafter.

90. We acknowledge that this is a dramatic increase, however it is the result of two specific and significant areas we consider are not addressed by the Financial Memorandum: the likely need for a new team of ‘Authorised Investigating Persons’, described in the Policy Memorandum but not addressed at all within the Financial Memorandum; and the need to maintain an on-going awareness-raising campaign regarding presumed consent and opt out. The basis for our calculations is included in the paper submitted to the Finance Committee, which is included as an Annex to this document.

Costs/Savings to the NHS

91. The Financial Memorandum does not provide any defined estimate of overall costs/savings to the NHS or to Scotland. Rather, it sets out some of the ways in which savings or benefits can be calculated. From the perspective of Scottish Government, any long term costs/savings analysis to NHS Scotland and NHS Health Boards are difficult to calculate until the impact of the legislation – i.e. the number of additional donors and transplants – is understood. Given there is no estimate provided in the supporting documentation for the Bill of the likely number of additional donors that will flow from the legislation, it is difficult to assess potential costs/savings.

Conclusion

92. In our view the Bill’s Financial Memorandum significantly underestimates the potential costs of the legislation to Scottish Ministers – a difference of approximately £16 million over 10 years.
93. There is also a lack of clarity on the potential costs to the NHS since there is no estimate provided on the potential increase in donors and transplants resulting from the legislation.

94. Whilst high or unknown costs are not, in themselves, a barrier to implementing any measures which would improve or save lives, they are significant in the context that there is no certainty that this Bill will achieve its aim, and no information provided on the number of additional donors to which it is expected the legislation would lead.

9. Consultation

95. Ms McTaggart first lodged a proposal and consultation for a move to presumed consent with opt-out, in June 2014.

96. The consultation, which closed on 23 October 2014, garnered 559 responses, mostly from individuals. The consultation analysis noted that although individuals were ‘broadly in favour’ this may have been at least partly due to the fact that the online survey ‘was promoted by organisations actively campaigning for a change in the law’. It also noted that ‘support for the proposal was much more equivocal among the organisations that responded’.

97. Although there was an open public consultation, it is not clear the extent to which the proposals in the Bill have actually been tested with the professionals who are actually involved in supporting patients who may become organ donors (intensive care clinicians), those who carry out transplant operations (transplant surgeons) and those who support the donation process (Specialist Nurses in Organ Donation). The Scottish Government believes it is important that those who would actually work under the proposed legislation should have the option to provide evidence in response to the Bill.

98. Other key organisations such as NHS Blood and Transplant, the British Transplantation Society and the UK Donation Ethics Committee should also be able to provide evidence as part of the scrutiny process.

Scottish Government
To: Scottish Parliament Finance Committee

31 August 2015

TRANSPLANTATION (AUTHORISATION OF REMOVAL OF ORGANS ETC.) (SCOTLAND) BILL

Introduction

1. We note the recent Call for Evidence as regards the financial implications of the Member's Bill, title as above, from Anne McTaggart MSP.

2. We understand key organisations will be responding to the specific questions set out in the Call. This paper sets out the Scottish Government’s factual commentary on the Bill’s Financial Memorandum.

The Bill

3. The Bill's Policy Memorandum states that ‘the overall aim of the Bill is to increase the number of organs and tissue made available for transplantation in Scotland, and hence to allow more transplants to be carried out, reducing waiting lists and saving lives.’

4. The Bill does not provide an estimate for the number of additional donors, or transplants, to which the legislation would lead.

The Financial Memorandum

5. The Financial Memorandum’s overall costs are a stated estimate of £7.5 million over ten years, all of which are costs to Scottish Ministers, however – once interrogated a little further – our assessment of what the Financial Memorandum actually says is that the total cost to Scottish Ministers would actually be £6.1 million.

6. Some of the costs in the Bill have been arrived at by extrapolating from estimates provided to the Welsh Assembly during its deliberations on its own opt-legislation and others are not quantified but are noted as being offset by savings achieved through e.g. the benefits gained from increased transplant numbers.

7. Our overall view is that it is impossible to accurately assess the costs of the proposed measures from the limited information contained within the Financial Memorandum. To assist the Committee at this early stage however, we have attempted to extrapolate some costs from the information contained within the Financial Memorandum and provide:

- our view on the accuracy of these costs,
- our own revised estimates (where possible), and
• additional comment and estimated costs on specific areas of expenditure we believe are missing.

Summary of Original Costs versus SG Revised Costs

Costs to Scottish Ministers

8. While the Financial Memorandum suggests costs to Scottish Ministers might be in the region of £6.1 million over 10 years (see Table 1 in Annex A) our own calculations suggest that implementing the Bill as drafted would have a cost closer to £22.2 million over ten years, and with recurring costs of circa £2 million each year thereafter (see Table 5 in Annex A).

9. We acknowledge that this is a dramatic increase, however it is the result of two specific and significant areas we consider are not addressed by the Financial Memorandum: the likely need for a new team of ‘Authorised Investigating Persons’, described in the Policy Memorandum but not addressed at all within the Financial Memorandum; and the need to maintain an on-going awareness-raising campaign regarding presumed consent and opt out. Both are explained in more detail within Annex A to this paper.

Costs / Savings to the NHS

10. The Financial Memorandum does not provide any defined estimate of overall costs / savings to the NHS or to Scotland. Rather, it sets out some of the ways in which savings or benefits can be calculated. From the perspective of Scottish Government, any long term costs/savings analysis to NHS Scotland and NHS Health Boards are difficult to calculate until the impact of the legislation – i.e. the number of additional donors and transplants – is understood. Given there is no estimate provided in the supporting documentation for the Bill of the likely number of additional donors that will flow from the legislation, it is difficult to assess potential costs/savings.

11. Annex B to this paper provides some commentary around potential costs for the NHS, but we are not in a position to provide firm costs / savings at this time.

Conclusion

12. This paper provides a factual analysis of the Financial Memorandum for the Bill. In our view it significantly underestimates the potential costs of the legislation to Scottish Ministers – a difference of approximately £16m over 10 years. There is also a lack of clarity on the potential costs to the NHS as a result of there being no estimate provided on the potential increase in donors and transplants which the legislation would be expected to lead to.

13. The Scottish Government will respond to the lead committee in due course in respect of its position on the Bill more generally.

Scottish Government

August 2015
COSTS TO SCOTTISH MINISTERS

Costs As Set Out within the Financial Memorandum

1. The Financial Memorandum states at paragraph 17 that ‘the estimated overall cost of £7.5 million over 10 years for the Wales Act seems a reasonable overall estimate for this Bill, too’. From looking at the detail set out in paragraphs 13- our interpretation of the Financial Memorandum’s overall costs to Scottish Ministers is actually somewhat lower, at £6.1 million.

2. The Memo’s starting point is a specific list of costs required to implement opt out in Wales, which are then adjusted to reflect the Scottish population. Table 1 interprets the financial information provided in the Bill into specific, albeit indicative only, costs. It is clear from Table 1 that the total identified estimated costs for the Scottish Ministers is £6.1m, mainly incurred over the first two or three years.

Table 1. Estimated costs to Scottish Ministers over 10 years as suggested within the Financial Memorandum

<table>
<thead>
<tr>
<th>Spend Area</th>
<th>Cost £m</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publicity Campaign</td>
<td>2.8</td>
<td>1 year campaign, Welsh costs x 1.7</td>
</tr>
<tr>
<td>Business Change Management</td>
<td>0.1</td>
<td>Welsh costs x 0.2</td>
</tr>
<tr>
<td>IT Changes (NHsbT Register)</td>
<td>0.5</td>
<td>Welsh costs x 0.2</td>
</tr>
<tr>
<td>Process additional registrations</td>
<td>1.7</td>
<td>Welsh costs x 1.7</td>
</tr>
<tr>
<td>Notify 16 year olds</td>
<td>0.3</td>
<td>Welsh costs x 1.7; Welsh 17yrs; Scotland 16yrs.</td>
</tr>
<tr>
<td>Evaluation</td>
<td>0.2</td>
<td>No change</td>
</tr>
<tr>
<td>Clinician training</td>
<td>0.5</td>
<td>Welsh costs x 1.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>6.1</strong></td>
<td></td>
</tr>
</tbody>
</table>

3. Two of the areas in Table 1 (publicity campaign and clinician training) are covered in more detail below. A further area, that of Authorised Investigating Person (AIP), is not mentioned at all in the Financial Memorandum, but is likely to give rise to costs. This is discussed below.

Publicity / Marketing Campaign

4. The Bill’s Policy Memorandum recommends a minimum six month awareness raising campaign, but its Financial Memorandum instead suggests costs for a 1 year campaign of £2.8 million. These proposed costs for the campaign are acknowledged within the Financial Memorandum as high when compared against the 2012/2013 published Scottish Government marketing spend on organ donation of £527k. Since 2012/13, however, the Scottish Government organ donation marketing budget has been reduced by half. The
The proposed cost is therefore even higher in comparison to the current available budget.

5. The Scottish Government’s own indicative costs for a Scottish campaign to support this legislation are broadly similar to those within the Financial Memorandum. Although the costs within it have been informed by the campaign in Wales, it is important to recognise that Scotland is in a different starting position, having consistently run media and advertising campaigns for organ donation since 2007. Rather than a campaign run over a minimum of six months, we have benefited from the lessons learned from previous Scottish campaigns and from the Welsh experience. A Scottish campaign would therefore involve targeted messages delivered at particular key stages, with campaign costs incurred over either one or two years, depending on the implementation schedule for the legislation itself.

6. The higher than usual campaign costs reflect the need, in this instance, to ensure the key messages reach all adults age 16+ in Scotland. The campaign needs to reach as wide an audience as possible and therefore includes a variety of communication channels. TV advertising is included because we know this generates the highest levels of awareness. Awareness is also higher the more communications people experience. For both these reasons, the campaign proposal contains a mix of TV, radio, direct mail and digital, which results in higher costs.

7. We have also identified the need for a recurring campaign to prevent a general drop in awareness after the initial year or two. Particularly important is the need to inform those turning 16 each year that, under the legislation, they would now be considered to be willing to be donors unless they opt-out. These recurring costs are particularly high when viewed within the same ‘ten year costs’ format taken by the Financial Memorandum (see Table 5 below).

Table 2: Scottish Government Indicative Marketing Campaign Costs

<table>
<thead>
<tr>
<th>Spend Area</th>
<th>Year 1 (£m)</th>
<th>Year 2 (£m)</th>
<th>Recurring (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency Fees &amp; Production</td>
<td>0.770</td>
<td>0.320</td>
<td>0.165</td>
</tr>
<tr>
<td>Creative Testing</td>
<td>0.020</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Media</td>
<td>n/a</td>
<td>0.700</td>
<td>0.200</td>
</tr>
<tr>
<td>Direct Marketing</td>
<td>n/a</td>
<td>1.150</td>
<td>0.175</td>
</tr>
<tr>
<td>Evaluation</td>
<td>0.025</td>
<td>0.050</td>
<td>n/a</td>
</tr>
<tr>
<td>Other / Staff</td>
<td>0.09325</td>
<td>0.1635</td>
<td>0.0795</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>0.90825</strong></td>
<td><strong>2.3835</strong></td>
<td><strong>0.6195</strong></td>
</tr>
</tbody>
</table>

or £3.29173 over one year

8. A significant measure within the Bill’s Policy Memorandum and referenced at paragraph 3 of the Financial Memorandum is that, unless they opt out, presumed consent would apply to anyone resident in the country for over six months. This has significant implications for temporary residents in Scotland, for example international students and foreign contractors, who would be unlikely to even consider the issue of organ donation and what the new system might mean for them and their families, unless they are clearly
notified and informed. As such, costs for notifying this group are contained within the ‘main’ initial campaign, but will also require to be a key feature of the identified recurring awareness raising campaign.

9. The Financial Memorandum suggests at paragraph 20 that ‘The size of the Scottish Government’s advertising budget is such that it could prioritise the publicity campaign required by the Bill without necessarily increasing its overall advertising expenditure (although this would require some general re-prioritisation, for one year only, from other portfolios in favour of health)’. The identified cost taken over one year, would be almost half the Scottish Government’s total (i.e. not just health-related) marketing budget. If taken over two years, the costs would still be - in both those years - roughly equal to the Scottish Government’s entire annual Health and Social Care marketing budget. Additional funding would have to be identified for costs above the existing baseline.

Clinicier Training / NHSBT

10. Estimated ‘clinician training’ costs are not explicitly provided within the Financial Memorandum, but there is a suggestion that these would amount to approximately £500k in costs to Scottish Ministers (as per Table 1 above). We do not disagree with this general figure, but feel it may be more helpful to provide a breakdown of how that approximation may be reached.

11. Training can be broken down into different areas. For NHSBT it would encompass Scottish Specialist Nurses – Organ Donation (SNODs) training and also UK-wide SNODs’ awareness training. For NHS Scotland / Health Boards it would encompass awareness-raising for all current and incoming clinical staff. All such training would need to be developed and delivered prior to implementation of any new system.

12. Table 3 below sets out some indicative costs for this training / awareness raising. It uses a figure obtained from NHSBT in relation to broad awareness-raising for all SNODs across the UK, and also includes a notional figure for some further targeted training of Scottish SNODS on the new system. It is also based on a preferred SG / NHS Education Scotland model of developing online module/s for medical staff which can then be undertaken by all staff during time already allocated to continuing professional development requirements.

Table 3: Staff Training and Awareness Raising Indicative Costs

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Spend Area</th>
<th>Cost (£000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSBT</td>
<td>Scottish SNODS specialist training</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>UK SNODS awareness raising training</td>
<td>360</td>
</tr>
<tr>
<td>NHS Scotland / NHS Boards</td>
<td>Online Modules Development &amp; Dissemination (NHS Education Scotland)</td>
<td>140</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>£600</strong></td>
</tr>
</tbody>
</table>
The Role of the Authorised Investigating Officer (AIP)

13. The Bill and its Policy Memorandum introduces a new role of ‘Authorised Investigating Person’ (AIP). The role of the AIP will be to check that the deceased has either opted in or opted out; whether or not they had appointed a proxy and if any such proxy is available and able to make a decision at the point of donation. In the event that there is no proxy appointed, then a series of further checks will be made with the nearest relatives, including whether the deceased person had no reasonable opportunity to opt out in the previous six months. If any applicable information comes to light that indicates the deceased did not have a reasonable opportunity to opt out, then the draft legislation allows the AIP to stop a donation from proceeding.

14. The role is described as one which would be undertaken by ‘health professionals’, but with no further elaboration. Although described as an optional or possible role, rather than a requirement for the new system, the role description would suggest otherwise, as no role currently exists that could accommodate all of the specified functions in addition to their normal responsibilities.

15. There are different options for delivering the AIP function, but for the purposes of this factual commentary on the Financial Memorandum we have considered the costs for the creation of an AIP team. Elements of establishing this type of team i.e. creating and recruiting for a new statutory role and then centrally managing this team of specialists who would work with families and NHS staff across different locations, have some similarities to the recently created team of Medical Reviewers (MRs) who are managed by Healthcare Improvement Scotland to monitor and improve the accuracy of the completion of cause of death forms (MCCDs) across Scotland. The overall costs for establishing this team might well be a useful comparison for a new AIP team, given that the variation in pay band between the MRs and their assistants would be roughly equivalent to the total on-going salary costs of a slightly larger team of circa 18 AIPs at Agenda for Change Pay Band 7, to match SNODs. Table 4 provides an initial estimate of the possible costs of a new AIP team, informed by the MR experience.

Table 4: Costs to NHSBT for new AIP Team over 10 Years

<table>
<thead>
<tr>
<th>Spend Area</th>
<th>Year 1 (000)</th>
<th>Year 2 (000)</th>
<th>Recurring (000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role Development &amp; Recruitment</td>
<td>20</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Initial Training</td>
<td>100</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Salary, OT etc</td>
<td>n/a</td>
<td>1200</td>
<td>1200</td>
</tr>
<tr>
<td>Totals</td>
<td>£120</td>
<td>£1200</td>
<td>£1200</td>
</tr>
</tbody>
</table>

Conclusion

16. Table 5 below sets out our revised estimate of the potential costs to Scottish Ministers. It amounts to total costs to Ministers of **£22.2 million** over ten years, with some recurring costs to Ministers beyond that of circa **£2 million** per year.
<table>
<thead>
<tr>
<th>Spend Area</th>
<th>Cost £m</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publicity Campaign</td>
<td>3.3</td>
<td>See Table 2. Over 1 or 2 years, depending on implementation schedule.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.9</td>
<td>See Table 2. Recurring £620k per year for 8 years (and beyond)</td>
</tr>
<tr>
<td>Business Change Management</td>
<td>0.1</td>
<td>No change from Financial Memo</td>
</tr>
<tr>
<td>IT Changes (NHSBT Register)</td>
<td>0.5</td>
<td>No change from Financial Memo</td>
</tr>
<tr>
<td>Process additional registrations</td>
<td>1.7</td>
<td>No change from Financial Memo</td>
</tr>
<tr>
<td>Notify 16 year olds</td>
<td>0</td>
<td>Now included within Publicity Campaign costs</td>
</tr>
<tr>
<td>Evaluation</td>
<td>0.2</td>
<td>No change from Financial Memo</td>
</tr>
<tr>
<td>Clinician training</td>
<td>0.6</td>
<td>See Table 3.</td>
</tr>
<tr>
<td>AIP Costs</td>
<td>10.9</td>
<td>See Table 4. Recurring £1.2m for 9 years (and beyond)</td>
</tr>
<tr>
<td>SG Total</td>
<td>22.2</td>
<td></td>
</tr>
</tbody>
</table>
COSTS TO NHS SCOTLAND AND NHS BOARDS

Costs As Set Out in the Financial Memorandum

1. The Financial Memorandum does not set out specific costs or savings to NHS Scotland. Rather, this section of the FM instead sets out a number of general ways in which savings against costs may be made as a result of the implementation of the legislation. At the very close of the memorandum, it states ‘There will also be costs associated with an increase in the number of transplant operations. However, these financial costs could be offset by the long-term savings of a reduction in the burden of the health service through reduced dialysis provision and associated long-term care costs’.

2. Although a little unclear, the overall implied position appears to be that the financial benefits generated from any additional transplants will offset any and all extra costs to NHS Boards over time, and therefore all costs can be accommodated from within existing Board budgets. This is a very generalised assumption and would need detailed discussion with NHS Board Chief Executives. It is not clear the extent to which this point has been tested with NHS Boards.

3. If the Bill achieved its aim of increasing the numbers of transplants in Scotland, there would be a direct, upfront extra cost to the NHS for each additional transplant and for at least the first three years of post-operative treatment for each transplant recipient. We note that this is acknowledged to some extent in paragraph 31 of the Financial Memorandum, but no specific figures in terms of upfront extra costs are provided. This is linked to the fact that the Financial Memorandum does not at any point estimate how many additional donors – and by extension, the number of additional transplants – the legislation would lead to.

4. Additionally the Financial Memorandum mentions savings to the NHS medical management costs achieved by the fact that post-operative care costs are significantly less than pre-operative care. This is not in dispute. We are required, however, to make the point that – with the exception of kidney transplants – patients who do not receive a transplant will die. This is, of course, a critical and urgent reason for the provision of care, not the avoidance of it, but for the purposes of financial accuracy and NHS budget planning it cannot be said that there are direct financial savings to be made where any post-operative care costs exist. An increase in transplants (other than kidney transplants), whilst undoubtedly desirable and something to strive for, will result in immediate higher costs to the NHS that require to be clearly acknowledged, even if these costs are immediately accepted as inevitable and worthwhile. For exactly this reason, NHS National Services Division has undertaken a great deal of work to forecast the potential costs of additional transplants arising out of the Scottish Government’s Donation and Transplantation Plan for Scotland, over the period 2020. NSD has undertaken detailed consultation with NHS Boards to ensure resources will be made available to support these additional costs.
5. There are other broader benefits and savings that would, over time, offset some or all costs associated with extra transplants e.g. the economic benefits of transplant recipients returning to work or possible reduced Local Authority social care costs. Both such savings are mentioned within the Financial Memorandum. These, however, would not be direct savings to the NHS in Scotland. The Welsh Assembly used a similar broad costs / savings analysis and reached a headline conclusion that their system would ‘break even’ from just one extra transplant per year. This work has undoubtedly informed the Financial Memorandum for this Bill but it is important to note that the proposals within the Ms McTaggart’s Bill are not directly comparable to those being introduced in Wales.

6. As with the Financial Memorandum, but for different reasons, we are ultimately not in a position to provide any robust estimate of financial costs / savings to the NHS and to Scotland. It may be possible to provide a breakdown solely of the costs of e.g. one additional transplant in each of the key areas of kidney, heart, lung and liver, including follow-on care costs, but this would not assist in calculating overall costs to the NHS unless it was known how many additional transplants to expect. And as already noted above, neither the Financial Memorandum nor the Bill provide any estimate for likely additional donors and transplants. This is information is critical to accurately estimating the costs of the legislation.