

PROPOSED ORGAN AND TISSUE DONATION (SCOTLAND) BILL – ANNE MCTAGGART MSP

SUMMARY OF CONSULTATION RESPONSES

This document summarises and analyses the responses to a consultation exercise carried out on the above proposal.

The background to the proposal is set out in section 1, while section 2 gives an overview of the results. A detailed analysis of the responses to the consultation questions is given in section 3. These three sections have been prepared by the Scottish Parliament's Non-Government Bills Unit (NGBU). Section 4 has been prepared by Anne McTaggart MSP and includes her commentary on the results of the consultation.

Where respondents have requested that certain information be treated as confidential, or that the response remain anonymous, these requests have been respected in this summary.

This summary does include quantitative data in relation to the responses to some of the questions contained in the consultation document. This includes numbers and proportions of respondents who have indicated support for, or opposition to, the proposal. In interpreting this data, it should be borne in mind that respondents are self-selecting and it should not be assumed that their individual or collective views are representative of wider stakeholder or public opinion. The principal aim of the document is to identify the main points made by respondents, giving weight in particular to those supported by arguments and evidence and those from respondents with particular experience and expertise. It is important to note that a consultation is not an opinion poll and the best arguments may not be those that obtain majority support.

Copies of all the individual and organisation responses to this consultation are available on the following website www.annemctaggartmsp.com/campaigns. Responses have been numbered for ease of reference, and, where referred to in this document, the relevant number is included i.e. R1 is response number 1 received. .

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SECTION 1: INTRODUCTION AND BACKGROUND

Anne McTaggart MSP's draft proposal, lodged on 26 June 2014, is for a Bill to:

Amend the law on human transplantation, including by authorising (in certain circumstances) the posthumous removal of organs and tissue from an adult who had not given express consent.

The proposal was accompanied by a consultation document, prepared with the assistance of NGBU. This document was published on the Parliament's website, from where it remains accessible:

<http://www.scottish.parliament.uk/parliamentarybusiness/Bills/78936.aspx>

The consultation period ran initially from 26 June to 25 September 2014. However, due to the volume of responses being received and requests from potential respondents for more time, the consultation was extended for a further month and closed on 23 October 2014.

In total 52 organisations were sent copies of the consultation or links to it. These organisations included a wide range of churches and religious organisations, doctors' and nursing organisations as well as a range of voluntary and charitable groups, particularly groups with an equalities focus.

Separately, an online survey was created which asked the same questions as the consultation document and was widely disseminated by organisations campaigning for a change in the law. A large number of responses to this survey were received, including some in hard copy. For data protection reasons, these individual responses have all been treated as anonymous responses.

The consultation exercise was managed by Anne McTaggart MSP's parliamentary office and efforts to publicise the consultation process included the use of the MSP's social media outlets, press releases, Evening Times articles and Anne McTaggart promoting awareness by visiting British Heart Foundation shops in Inverness, Falkirk, Glasgow and Greenock.

The consultation process is part of the procedure that MSPs must follow in order to obtain the right to introduce a Member's Bill. Further information about the procedure can be found in the Parliament's standing orders (see Rule 9.14) and in the *Guidance on Public Bills*, both of which are available on the Parliament's website

- Standing Orders (Chapter 9):
<http://www.scottish.parliament.uk/parliamentarybusiness/26514.aspx>
- Guidance (Part 3):
<http://www.scottish.parliament.uk/parliamentarybusiness/Bills/25690.aspx>

SECTION 2: OVERVIEW OF RESPONSES

In total, 559 responses were received, of which 529 were from individual respondents, including 3 MSPs, and 30 were from organisations.

The 30 organisation responses can be categorised as follows:

- 16 from representative organisations: six churches and faith groups, two church parliamentary offices, five organisations representing medical practitioners, one community council, the Law Society of Scotland and the Scottish Youth Parliament.
- 10 from charitable organisations which were mainly concerned with medical issues.
- 4 from public sector organisations which deal with organ and tissue donation, such as the UK Donation Ethics Committee.

As noted above, all responses from individual respondents have been treated as anonymous.

Most individual respondents were broadly in favour of the proposal. This may partly be accounted for by the fact that the online survey (through which most of these responses were received) was promoted by organisations actively campaigning for a change in the law. Support for the proposal was much more equivocal among the organisations that responded.

Throughout this summary document, precedence has been given to the views of organisations (on both sides of the argument), particularly those with direct experience of how current arrangements work, and those representing the people who would be most directly involved in making any new legislation work in practice.

Churches and religious organisations questioned the ethical basis of the proposal, given that explicit consent to organ donation would no longer be required. There was a mixed response from public sector organisations, with one in support of a move to a soft opt-out organ donation approach, one opposed and two undecided.

A recurring theme across responses to a number of questions related to the recent move to an opt-out approach to organ donation in Wales. The Human Transplantation (Wales) Act received Royal Assent in September 2013 and is due to come into force in December 2015. A number of respondents suggested that Scotland should reflect on the impact this legislation has on donation rates in Wales before embarking on a change to the legislative framework in Scotland.

The importance of a comprehensive education and public awareness campaign was highlighted as a key factor in achieving the aims of increasing donation rates and reducing organ transplantation waiting times and this point was highlighted both by respondents who were supportive and those opposed to the proposal.

The majority of respondents felt the role of the donor's family was important. However, there were a range of views on whether they should be allowed to veto the removal of organs where the deceased's views are not explicitly known. There was

general agreement that any change to the current system should not result in additional stress for donors' relatives at what is already a very difficult time.

Respondents raised questions regarding the definition of 'nearest relative' and how the system would operate in relation to adults who are incapable of expressing their own views.

There was no consensus on whether prospective donors should be able to appoint proxies to make the final decision regarding transplantation on their behalf, but there was general agreement that any opt-out scheme should apply to adults living in Scotland only, with young people still being required to opt-in. There were a range of views as to what the exact cut-off age should be.

SECTION 3: RESPONSES TO CONSULTATION QUESTIONS

This section sets out an overview of responses to each question in the consultation document.

The consultation sought views on changing the system of organ and tissue donation registration from an opt-in system to a 'soft opt-out system' in Scotland. The basis of the proposed 'soft opt-out system' would be that organs and tissues could be removed posthumously from an adult who had not registered or expressed an objection during their lifetime. In contrast, the current opt-in system of organ and tissue donation encourages those wishing to become a donor to register on the NHS Organ Donation Register.

The consultation document summarised (p.5) the key features of the proposed soft opt-out system as being:

1. All adults aged 16 or over who reside in Scotland would have the right to register an objection to some or all of their organs being used for transplantation after their deaths;
2. The family of a deceased person will be consulted at the time of death to establish any objection of the deceased that had not been registered;
3. Young persons under 16 years not covered by the opt-out system will continue to be able to opt in as potential donors; and
4. The proposal would only cover donation of organs and tissues for transplantation; uses for research or other purposes will not be covered.

General aim of proposed Bill

Question 1

The overarching purpose of my proposal is to move from the current opt-in system to a soft opt-out system of organ donation. Do you support this move? Please indicate 'yes / no / undecided' and explain the reasons for your response.

Almost all individual respondents answered this question, with strong support for the proposal:

- A significant majority, 423 (80%), supported the proposal.
- 86 (16%) did not support the proposal.
- 19 (3%) respondents were undecided.
- One respondent did not answer the question.

There was less clear support for the proposal among the 30 organisations:

- 11 (36%) supported the proposal.
- 12 (40%) did not support the proposal.
- Of the remaining seven organisational respondents, four were undecided and three did not answer this question.

Reasons for supporting the proposal

Many respondents said that moving to a soft opt-out system would increase the number of organ donations and thereby bridge the gap between the demand for organs and the current level of donation. Comments included:

- We know that nine out of ten people in Scotland support organ donation, but less than 40% have actually joined the Organ Donation Register. There is clearly a yawning gap between good intention and action. British Heart Foundation (BHF), R 426]
- Studies show that a large majority of people would be willing to donate organs after their death but only 31% of the UK population are on the NHS Organ Donor Register. While this level of apathy exists, despite people's good intentions, people will continue to die while waiting for donor organs". [British Medical Association (BMA), response 429)]
- I believe people would have the intention of donating organs but just don't get around to actually signing up for it. This method would encourage people who want to opt-out to do so, possibly leading to more organ donations. [R 11]
- Yes, when 95% of people would be content to donate organs after death but only 40% are on the organ donation register it is clear that too many people just haven't got round to adding their name to the register. It is sensible and progressive to move to a system that can deliver these organs while also respecting the rights of those who wouldn't want to donate after death for any reason. The proposed Bill clearly meets these 2 requirements. [R 166]

An observation made by BHF was that donation rates were higher in countries with opt-out systems such as Spain, Belgium and Norway and suggested that a change in the law to move to an opt-out system would facilitate greater awareness and discussion around organ donation, a point which was echoed by many witnesses:

- a legislated system of consent will heighten the national debate around transplantation and encourage people to discuss organ donation with their friends and families while they are still alive. [Cystic Fibrosis Trust (CFT), R 438]
- The proposal would make people have the conversation with their loved ones prior to an event that would require it. [R 46]

Reasons for not supporting the proposal

A recurring theme amongst organisations, and in particular responses from religious organisations, was to oppose the proposal on the grounds that it would undermine the principle of individual consent and the integrity of the individual. The following quotes below provide a sense of this perspective on the proposal:

- 'Presumed consent' in an opt-out system is based on the unfounded assumption that every single person who has not opted out was aware of the opt-out provision and has consciously taken a decision not to opt-out. [Free Church of Scotland, (CoS) R 416]

- An opt-out system cannot guarantee that the very important informed explicit consent principle is always respected”. [Christian Medical Fellowship, (CMF) R 417]
- Organ donation is an altruistic act and should involve the voluntary giving – not taking – of organs as a free gift in the context of fully informed consent. [Christian Concern & Christian Legal Centre, (CCCLC) R 435]
- The Orthodox Jewish Community¹ was concerned that an opt-out system would unnecessarily limit the number of donors as some people who did not in principle object to donating their organs, would inevitably opt out of such system from a fear that it risked contravening Jewish religious law. [Scottish Council of Jewish Communities (SCoJeC) R 464]
- the presumed consent system is ethically questionable ... there is a very real danger that a system of presumed consent could undermine donation as an entirely altruistic gift. [Christian Action Research and Education (CARE) R 463]

A number of respondents believed the opt-in system currently in operation already accomplishes what the proposals set out to achieve. The Scottish Council on Human Bioethics (SCHB) argued that Scotland currently has a hybrid system and was concerned that there is currently no fail-safe mechanism to allow people to record their wishes on organ donation. It recommended that the existing legislation should be reformed so as to implement an opt-in system requiring explicit consent. [Scottish Council on Human Bioethics – SCHB, R 437]. Other comments included:

- a Spanish-style “opt-out” system is already largely operating in Scotland. [CoS, R431]
- We do not favour legislative change and instead support NHS Blood and Transplant’s focus on ‘changing public behaviour with regard to organ donation’ and ‘maximising conversion of potential donors into actual donors’ by means other than adoption of an opt-out approach to consent [Royal College of Nursing Scotland (RCNS), R555]
- A conflict of interest may well be perceived where a health care professional is both responsible for the decision to commence end of life care for a patient as well as being responsible for identifying that patient as a potential organ donor. [Intensive Care Unit professionals at the Southern General Hospital in Glasgow, R415]

Other comments on the general principle of the proposal

The Law Society of Scotland (LSoS) was neither supportive of nor unsupportive of the proposal, but stressed that any change to the legislation must be clear and transparent in its aims and objectives and it must involve a publicity campaign which

¹ The response from the Scottish Council of Jewish Communities - the representative body of Jewish communities in Scotland, the majority of whom are affiliated to Orthodox Judaism - although strongly supportive of organ donation and transplantation, held a range of views with regard to the general principle of the proposal. The Orthodox and Reform Jewish Communities supported the continuation of the current opt-in system whereas the Liberal Jewish community was strongly in favour of an opt-out system.

is accessible and tailored to accommodate all diverse groups currently living in Scotland. [Law Society of Scotland. [LSoS, R 467]

The British Transplantation Society (BTS) supported the proposal but highlighted some concerns around the practicalities saying that a soft opt-out scheme must ensure that individual consent is valid over time and that healthcare professionals must to continue to have the confidence to explore options with donor families within an appropriate framework. [British Transplantation Society (BTS), R 554]

The UK Donations Ethics Committee (UKDEC), although having no fundamental ethical objection to a soft opt-out system, mentioned adults with incapacity:

- On a practical and legislative level, the proposal needs to be clear on the consent status of a potential donation after circulatory death donor who may not have opted out, but is still alive and lacking capacity at the time of decision-making about donation. [UK Donations Ethics Committee R 462].

The situation in Wales was mentioned by a number of respondents, a recurring theme across responses to a number of questions. CARE made the point that Wales was the only country in the UK to see a fall in the number of organ donations between 2011/2012 and 2012/2013, suggesting this may explain the Welsh Government's decision to introduce presumed consent legislation and SCoJec stated:

- In principle, the Liberal Jewish community is strongly in favour of an opt-out system, but recommends delaying legislation until it is known how the new system is working in Wales, and whether or not it is providing the intended benefits. [Scottish Council of Jewish Communities R 464 (SCoJeC)]

Legislative change

Question 2

a) How essential is it to change the law (from an opt-in to a soft opt-out system) in order to achieve the intended benefits (increased transplant rates, reduced waiting lists)?

b) Are there other (non-legislative) measures that could achieve similar outcomes without the need for legislation?

Just over half of the individual respondents, 273 (51%), felt it was essential and 68 (13%) did not; 169 (31%) did not answer the question and 19 (3%) were undecided.

Four organisations (13%) felt a change in the law was essential and 12 (40%) did not. Eleven (36%) did not answer the question and three (10%) were undecided.

A third of organisations (10) answered the second part of the question agreeing there were other non-legislative measures that could achieve similar aims, two (6%) disagreed, 13 (43%) did not answer the question and the remaining five were undecided or it was unclear.

Among the individual respondents, 79 (14%) agreed that non-legislative measure could achieve similar results to the aims of the proposal, while 100 (19%) disagreed, 325 (61%) did not answer the question and the remaining 25 were undecided or it was unclear.

Those in favour of a change in the law

The British Heart Foundation made the point that in 2013/14 Scotland's eligible donor rate was 61.8 per million population which equates to 328 possible donors and the average donor in Scotland donates 3.5 organs. It suggested that it would take 13 years to address the organ donor shortage without legislation as the reality is that for a variety of reasons, such as the fact that not all people die in circumstances that allow for organ donation, at present, two thirds of eligible donations do not occur.

The Organ Donation Taskforce report published in 2008 was referred to by a number of organisations including the BMA who said how a change in the law, in addition to infrastructure and organisational changes, could lead to increases in donation rates. It emphasised that a change in the law should be an integral part of an overall package of improvements. [BMA, R 429]

The need for significant transformational change involving increased public awareness and understanding about organ donation was raised by many respondents:

- It is difficult to see how this important and fundamental shift in attitude could occur to the same extent, without legislation introducing opt-out. [British Medical Association, R 429].
- In my opinion this type of legislation should follow an intensive public debate and education on the subject. [R 515].

The Royal College of Physicians Edinburgh made the point that, in practice, consent for organ donation is always sought from the next of kin and 'approximately 40% of families approached refuse consent for organ donation'. They argued that where the deceased was on the Organ Donation Register (ODR) then the next of Kin is less likely to refuse consent i.e. in only 10% of cases, compared to 50% where the deceased was not on the ODR. They stated:

- A higher rate of organ donation will reflect increased public awareness, societal attitudinal change to donation, and improved clinical infrastructure. [Royal College of Physicians of Edinburgh, (RCPE)R 432]

No change in the law required

A number of key themes emerged among organisations which did not believe a change in the law was essential, including:

- Ethical concerns.
- Religious objections.
- A lack of robust comparative data.

- Data security and the donor register.
- The impact on the relationship between medical practitioners and individuals.

The British Transplantation Society believed that it was open to question whether a change in the law is essential in order to achieve the intended benefits of the proposal and stated that the effects of opt-out laws on donation rates are hampered by differences in cultural attitudes, economic conditions, availability of intensive care units, number of transplant co-ordinators, degree of governmental support and other factors, whose influence may be important but uncharted. [British Transplantation Society, (BTS) R 554].

Questions were raised regarding the robustness of the comparative data used to measure the link between donation rates and the legislative framework. Christian Concern & Christian Legal Centre (CCCLC) argued that there was no clear international evidence to show that an increase in donations will result from a change in the law, citing Sweden, Spain, Ireland and the United States as countries where there appears to be no correlation between organ donation rates and the legislative framework for organ donation. [CCCLC, R 435].

Typical comments included-

- We believe organ donation is a gift and it should not become assumed or mandatory. [Intensive Care Unit professionals at the Southern General Hospital in Glasgow, R 415].
- The evidence linking opt-out systems with increased donation is equivocal or at best weakly in favour of opt-out having an effect. In order for confidence in the system to be upheld, those tasked with implementing it will need to be convinced that the time and resources involved could not be better deployed elsewhere. [UKDEC, (462)].
- The legislation itself may not be the major determining factor for organ donation as some countries with “opt-in” systems still have higher organ donation rates than countries which have adopted “opt-out” legislation. [The RCPE, R 432].
- Spain introduced ‘soft opt-out’ or ‘PC’ [presumed consent] legislation for organ donation in 1979 and now has the world’s highest rate of donation from deceased donors, so is cited as a model for introducing such laws. Yet Spain’s high deceased organ donor rate cannot reasonably be attributed to its PC laws. Instead, improvements in donor rates followed the implementation ten years later of a nationally organised organ donation system that included many innovations. [Christian Medical Fellowship, R 417].

A number of organisations believed no legislative changes should take place in Scotland until a proper assessment has been made of the impact of the implementation of the Human Transplantation (Wales) Bill. Among those who advocated waiting to see the impact of the Wales legislation were:

- Church of Scotland, (CoS)R 431.
- Kidney Research UK (KRUK), R 434.
- Scottish Council on Human Bioethics – SCHB, R 437.
- UK Donations Ethics Committee, R 462.

- British Transplantation Society, Ethics Committee , R 554.
- Scottish Episcopal Church, R 439.

Non legislative measures

The Law Society of Scotland (LSoS) commented that, although opt-out may have improved donation rates in other countries, this would not necessarily translate to other countries due to cultural differences and perceptions. [LSoS, R 467]

Many organisations believed that improving organ donation rates must also involve a number of other measures:

- It is generally accepted that the UK’s inability to convert potential donors into actual donors in a significant number of cases contributes to the shortfall, so the on-going work must be supported and investment in Organ Donation co-ordinators, Specialist Nurses and Clinical Leads sustained. We believe we cannot afford for a change in the consent system to distract attention away from the need to improve the systems and infrastructure around organ donation in the UK. [Cystic Fibrosis Trust – CFT, R 438].
- Currently, more organs could be used for transplantation but we need to improve infrastructure and clinical practice and there is a need for more research into graft viability, reducing rejection and increasing the life of transplanted organs’. [Kidney Research UK – KRUK ,R 434].
- To boost organ transplants there needs to be more transplant co-ordinators, intensive care beds, organ retrieval teams and improved public awareness. [Christian Medical Fellowship, R 417].
- Better education of the public – starting in schools – and more sympathetic handling of relatives at the time of death will be more effective in the long run. [Free Church of Scotland, R 416].

Question 3

I believe the role of the family should be limited to being consulted on whether they are aware of any (unregistered) objection by the deceased rather than asking for their consent. Do you agree? Please indicate “yes/no/undecided” and explain the reasons for your response.

The majority of individual responses, 340 (64%), agreed with limiting consultation with the family to situations where the deceased’s wishes are unknown; 110 (20%) disagreed; 69 (13%) were undecided, and 10 did not answer the question.

Five (16%) organisations agreed with the question, 10 (33%) disagreed and six (20%) were undecided. Nine (30%) did not answer the question.

Those in favour of limiting the role of the family to being consulted believed that it still maintained a role for the family in the decision making process while ensuring the rights of the deceased remained paramount. The British Heart Foundation stated that changing the way we register consent via soft opt-out offers the opportunity for conversation around organ donation and could help make a difficult decision at a difficult time easier. [BHF, response 426]. The Scottish Youth Parliament stated that

if a young person makes the decision to register as an organ donor, their family should not be able to overturn that choice. [SYP, R 427]

Those organisations who disagreed with this approach questioned whether a situation was morally acceptable where organs are donated without explicit consent. FCS acknowledged that the declared wishes of the deceased person are paramount and relatives should not be able to override the deceased's decision. [FCS, R 416]

The majority of those undecided stressed the importance of involving the family and that the process of donating organs and that organ donation should not be seen simply as a statutory process, rather it should be seen as gift. Typical comments included 'it is important that the family are still involved in the process and see donation as a 'gift of life' and not a statutory process'. [Revival, R 252]

Whether or not relatives should have the right to veto a person's decision where the deceased's view was known was raised by a number of those who disagreed with limiting the role of the family. Christian Medical Fellowship made the point that, under an opt-out system, the removal of organs is only acceptable if the nearest relative was absolutely certain that this was the wish of the deceased, that they were fully aware of the authorisation and that they had not objected to the procedure. They went on to say that 'consent underlies the relationship between a doctor and patients and their families'. The following reasons were given as to why relatives should be able to veto:

- Increased distress in circumstances where families have no power in the decision making process.
- Cultural sensitivities.
- Lack of trust between clinicians and patients. R417 (CMF)

A number of respondents made the point that it was important to define the 'nearest relative'. It was suggested it should be defined as someone who knew the deceased person well and that relatives should not feel ignored or bypassed at such an emotional and difficult time. R416 (Free Church of Scotland). The LSoS believed that a consistent approach should be taken and highlighted that the definition in the Human Transplantation (Wales) Act 2013 is inconsistent with the current definition in Scotland (s.50 of the Human Tissue (Scotland) Act 2006). Law Society of Scotland [LSoS, R 467]

A recurring point made by respondents was that this an extremely difficult and painful time for donors' relatives and it was important they were treated sensitively and not ignored or by-passed when it came to organ donation. [FCS, response 416] There was concern among those against this approach that public confidence in the process and trust in the medical profession could be jeopardised:

- public confidence in a soft opt-out system could be quickly undermined and clinicians placed in very difficult positions. [RCPE. R 432]
- It would be hard to imagine circumstances where their wishes would be dismissed, especially where such a move would cause serious emotional stress. [KRUK, R 434]

- Support for donation is broad but shallow, and any perception that clinicians may have different priorities in caring for a dying patient could undermine that support significantly. [UKDEC, R 462]
- My belief is that family with objections to donation should be able to make these clear to the lead transplant nurse/physician (or other relevant clinician in charge), who would then make a final decision based on a range of factors (which may include current need; family distress; nature of death). The law should provide clear framework for making this balance, rather than set a rule for all cases. [R 16]
- the proposed system would make it harder for relatives to object when they are faced with the realities of what organ donation involves e.g. the mechanics of organ retrieval, the delays and uncertainty of its timing, the abruptness of donation after death etc. The public needs to know and understand these harsh realities before we consider a change in the current system. Once they do and a significant majority want an opt-out system we can reconsider.[R 246]
- ‘there is a real danger that the provision in the Bill which enables health professionals to disregard the views of relatives may be subject to Judicial Review under Articles 8, 9 and 10 of the ECHR. Relatives could claim that their rights have been ignored if they were not properly consulted prior to organs being removed.’[CARE, R 463]

Scottish Council on Human Bioethics made the point that in the case where the deceased was a person lacking capacity to make a decision to donate organs, the nearest relative should be able to authorise or forbid the removal of organs. [SCHB, R 437]

The Cystic Fibrosis Trust warned of the dangers of limiting the role of the family through legislation as this could lead to a negative shift in opinion to organ donation which would run counter to the general principle of the bill. [CFT, R438]

The Law Society of Scotland agreed that the wishes of the potential donor should be paramount but were undecided in other respects such as whether relatives should have the power to veto if their relative had not formally opted out.

Question 4

Do you think an individual should be able to appoint a proxy to the make the final decision regarding transplantation on their behalf? Please indicate “yes/no/undecided” and explain the reasons for your response.

Just under half of individual respondents (263, 49%), agreed with the ability to appoint a proxy, 151 (28%) disagreed, 102 (19%) were undecided and 13 (2%) did not answer the question.

Among the organisations, 11 (36%) agreed that an individual should be able to appoint a proxy and four (13%) disagreed; 12 (40%) did not answer the question and 3 (10%) were undecided.

Some of those in favour of an individual being able to nominate a proxy caveated their support saying that that no organs should be removed from the deceased if there is no expressed desire to donate, no proxy appointed and no close relative available to confirm the deceased's wishes. Comments in support included:

- An individual should be free to designate a proxy decision maker to ensure that their wishes and interests are safeguarded. [Catholic Parliamentary Office, R 414]
- An individual may distant from or no longer in touch with family members and may consider family not the best placed to make the decision. If they want to nominate someone else then this options should be available.[BHF, R 426]
- An adult should be able to appoint a proxy in the event of incapacity and that both parties know and understand the decisions they enter into. A suggestion may be to have a third person agree to the decision.[CFT, R 438]
- the ability to appoint a Rabbi of their choice to act as proxy would enable individuals to consent to donate their organs secure in the knowledge that this would only be done in a manner consistent with Jewish religious life. [SCJC, R 464]
- Your proposals are consistent with our guidance to doctors on the appointment of a legal proxy.[GMC, R 556]

Although not in support of this aspect of the proposal, the BMA did not object, in principle, to people being able to nominate someone but were concerned that the more complicated the message, the more difficult it is to ensure that all members of society are aware of, and understand their options.

Concerns were also raised by those in support of the nomination of a proxy::

- This is in line with the approach taken in other areas of law and we agree that an individual should be able to appoint a proxy. However, some complex issues have arisen in relation to that role in other legislation. It can become a matter of substituted decision-making on what have been the preferences of the individual concerned. Again, advance publicity and media campaigns may alleviate some of these issues and help facilitate discussion. [LSoS, R 467]
- for this to work effectively, it is essential that there is a mechanism to ensure that the correct proxy is appointed, and that they are always acting according to the instructions of the deceased individual. ...we would recommend that the name of the proxy should be reviewed regularly e.g. every 3 years. [CoS, R 431]

The Royal College of Physicians and Surgeons of Glasgow were undecided and highlighted some of the perceived difficulties associated with the appointment of a proxy:

- we are concerned that it may be difficult to contact such a proxy and that documentation would need to be reliable and witnessed. [Royal College of Physicians and Surgeons of Glasgow – RCPSG, R 534]

Question 5

My proposal is that only adults should be automatically opted-in to be a donor. Younger persons would have to register to be a donor, by themselves or with parental consent as they currently do. This approach is I believe the best way to safeguard children and young people. Do you agree? Please indicate “yes/no/undecided” and explain the reasons for your response.

Among the individuals, 359 (68%) agreed that and 99 (18%) disagreed that only adults should be automatically opted-in; 52 (9%) were undecided and the remaining 19 (3%) did not answer the question.

Among the organisations, 13 (43%) agreed, two (6%) disagreed, three were undecided and 12 (40%) did not answer the question.

A number of respondents who strongly opposed the Bill stated that, should a soft opt-out system be agreed to, it was important that children should be required to opt in to the scheme. A point echoed also by those in favour of the proposal. The following comments give a flavour of the strength of feeling:

- We do not support the overall proposal but agree it should not be assumed for children. R534 (RCPSG)
- This is consistent with our guidance. However, I would highlight our advice that ‘the capacity to consent depends more on young people’s ability to understand and weigh up options than on age’. R556 (GMC)
- Children should not be part of an opt-out system. This particular proposal is anomalous in that it aims at safeguarding the integrity of a child’s consent yet the bill is based on bypassing a requirement for consent from adults on how their organs will be used. R414 (CPO)
- Yes, strongly disagree with opt-out but if introduced the carrying of donor card, registering on the Organ Donation Register should be sufficient indication of a persons wishes. R417 (CMF)
- Support that those aged 16 and over to be automatically opted in as organ donors. SYP believes young people aged 12 to 15 should be able to opt-in by giving their written consent and that parents should be able to consent to the transplant of organs for children under the age of 12. [SYP, R 427]
- It is necessary at all times to ensure the protection of minors and those without the capacity to give consent for themselves. Thus, we agree with the necessity for explicit consent for children and young people to be included in any automatic opt- in system. [Church of Scotland, R 431]

Question 6

Do you agree the age limit for an adult should be set at 16 years old? Please indicate “yes/no/undecided” and explain the reasons for your response. If you answered no, what would you consider a more appropriate age?

Among individuals, 356 (67%) agreed that the age limit should be set at 16, 114 (21%) disagreed, 42 (8%) were undecided and 17 (3%) did not answer the question.

Of the organisations, 8 (26%) agreed the age limit should be set at 16, four (13%) disagreed, 3 (10%) were undecided and 15 (50%) did not answer the question.

Most organisations who responded no, or were undecided when asked this question, believed that 18 years of age was a more appropriate age limit. Typical responses included:

- The UN Convention on the Rights of the Child proposes children to be those under 18 years of age. R414 (Catholic Parliamentary Office)
- 18 should be the age limit until the results of the implementation of the Welsh Act has been analysed. R416 (Free Church of Scotland)
- There are shades of opinion on this issue, given that patients under 18 are able to give informed consent for other medical procedures. However, a more explicit “opt-in” approach may be helpful for those under 18, particularly as it is likely to be their parents who are asked for consent to harvest organs. R432 (Royal College of Physicians Edinburgh)
- 18, as considered the age of maturity for other important life decisions R435 (Christian Concern & Christian Legal Centre - CCCLC)
- Seems incongruous that people aged 16 and 17 could have their organs removed without having given consent whilst still being considered to need the services of a named person. Clarification is needed as to whether the named person will be asked the views of a deceased young person on organ donation in cases where relatives are unavailable. Will the named person have authority to give approval for organ removal in cases where the views of a deceased child or young person aged under 16 are unknown and no relatives are available to be consulted. R463 (CARE)

Those who agreed that the age limit should be set at 16 years of age argued that it was in line with other legislation applying in Scotland, comments included:

- This is in line with the Age of Legal Capacity (Scotland) Act 1991. Also wish to see those under 16 have an opportunity to actively register their wishes. Currently no age limit for donation. R426 (BHF)
- Support that those aged 16 and over to be automatically opted in as organ donors. SYP believes young people aged 12 to 15 should be able to opt-in by giving their written consent and that parents should be able to consent to the transplant of organs for children under the age of 12. R427 (SYP)
- Yes, young people in Scotland are considered adults at age 16. In line with the Adults with Incapacity (Scotland) Act. R429 (BMA)
- We would agree that a lower age limit of 16 would be appropriate for any opt-out system which was introduced. R431 (Church of Scotland)

The Free Church of Scotland (Continuing), which did not support the proposal, made the following suggestions for amending the current legislation (Human Tissue (Scotland) Act 2006) namely:

- So that the nearest relative may no longer authorise the transplant of a deceased persons organs when the deceased person has not given that authorisation.

- The age at which children can authorise the use of their organs after death is raised from 12 to 18. [Free Church of Scotland (Continuing)– FCS (Continuing), R 557]

The Scottish Council of Jewish Communities found there was a difference of opinion in the community with views on the appropriate age ranging from ranging from 16 to 21. R464 (SCJC)

The point was made that the Human Transplantation (Wales) Act 2013 adopted the same age as that of the Human Tissue Act 2004 i.e. 18. The Law Society of Scotland noted that consent to organ donation is currently covered under the Human Tissue (Scotland) Act 2006 which provides that a child over the age of 12 can consent to organ donation without parental consent and, if in writing, this cannot be vetoed by family members or those with parental responsibility:

- We agree that the proposed age limit of 16 years old for automatic opt-in is appropriate and we further agree that the current age limit for express consent to organ donation, as set out in the 2006 Act is appropriate. However, in relation to consent of the child between the ages of 12 -16 years, we do suggest that there should be safeguards in place to ensure a child aged between 12 and 16, and who provides written consent in accordance with Section 8 of the 2006 Act, fully understands the nature of the authorisation and the nature of organ donation. [LSoS, R 467]

Question 7

Do you agree that the soft opt-out system should apply to people who have been resident in Scotland for a minimum period of 1 year prior to their death? Please indicate 'yes / no / undecided' and explain the reasons for your response.

Among the individual respondents, 266 (50%) agreed with the suggested residency period of 1 year, 144 (27%) disagreed, 104 (19%) were undecided and 15 (3%) did not answer.

Among the organisations, eight (26%) agreed with the question, four (13%) disagreed, three (10%) were undecided and 15 (50%), did not answer the question.

The British Heart Foundation noted that this suggestion was in accordance with similar legislation within the UK referring to the Human Transplantation (Wales) Bill. (R426)

The British Medical Association also referred to the Welsh legislation, and considered that this was a reasonable residency period but noted that the crucial factor was that individuals are made aware of the system and know what they need to do if they wish to opt-out before it applies to them. (R429)

Some respondents considered that this should be long enough to allow health records to be available and for the deceased to have had an opportunity to opt out. [RCPE R432]

Other respondents referred to the one year period being sufficient time for individuals who wish to opt out to gain knowledge of the system either through awareness campaigns (R22, 119, 216), discussions with a GP (R259, 297), or through general conversation (R115).

Respondents who disagreed with the proposed one year minimum residency period highlighted the perceived advantages of an opt-in system, and considered practical implications for families and staff.

The Christian Medical Fellowship (R417) stated it supported an opt-in system where the length of residency would have no impact and that a person could donate even if they have been resident in Scotland for less than a year prior to their death.

CARE (R463) opposed the proposal in principle and therefore disagreed with the suggested minimum residency period. It suggested that should such a system be introduced, it should not apply to visitors to Scotland or those with foreign nationality who reside in Scotland. These people should still have to opt in to the organ donor register.

Individual respondents who explained their reason for being against the proposed residency period included:

- R273 – No, this is an arbitrary time limit and not sure of the purpose of setting it.
- R281 – No, they come from different cultures so why should residence in Scotland ride roughshod over their beliefs.
- R369 – No, living in Scotland doesn't change the quality of the organs or the people. Donations should be considered for anyone who dies in Scotland.

Questions were raised regarding being able to establish the wishes of the individual or their families; taking account of different cultures and beliefs; and difficulties around establishing whether or not an individual was resident, for how long, and whether they were aware of the proposed system.

- The proposal risks placing a lot of additional burdens on staff in Scotland relating to deciding about residence in Scotland. It is not explicit as to how this decision will be made, and what consideration will be given to those such as students attending further education institutions in Scotland. Implementation needs to ensure all staff are fully trained and supported to help families through the process. Moreover, given the need for speed in order to achieve successful donation and transplantation of some organs, there are clearly ethical implications in imposing potential additional strains on already stressed relatives, who might often be the only immediate source of necessary information. (R462, UK Donation Ethics Committee)

The SCoJC (R464), while accepting that the one year minimum period “might not, on the face of it, seem an unreasonable length of time”, expressed concern that practical difficulties might “make its application difficult if not impossible”. They highlighted two concerns:

- Firstly, in many cases, staff will have no way of knowing whether someone who dies as a result of an accident has been resident in Scotland for one or ten years, or is a day-tripper from south of the border. Secondly, we are concerned that there is no reliable way of informing new residents in Scotland that, if these proposals were to become law, after a year they would be presumed to consent to be an organ donor unless they have actively opted out of the scheme.

Concerns in relation to donors' families were expressed by some individual respondents (R3, R98) while issues over students (R63, R80) asylum seekers (R220) and transient workers (R211) were also raised.

Other individual respondents raised the point of whether an individual would have had sufficient time or been sufficiently aware of the soft opt-out process, which was also a theme with some of those who were in agreement with the proposed minimum period of residency.

The LSoS [R 467] agreed that there should be a residency period but raised questions on potential difficulties over how any period of residency is to be ascertained—

How are healthcare professionals to know that the potential donor was not resident, since he or she would presumably have at least a short term Scottish address? Also, if residency for the period is to be continuous, how are healthcare professionals to establish this with certainty, bearing in mind that decisions about organ donation have to be made within a short timeframe? There may not be enough time for a thorough investigation of the deceased's residency status. Healthcare professionals will be forced to rely on information from the deceased person's relatives or companions in this country.

What if a healthcare professional acted upon incorrect information in good faith? Consideration should be given to providing a defence for clinical staff who reasonably rely on the information provided or who have taken reasonable steps in the circumstances to identify whether the deceased was a resident.

Throughout the responses – whether respondents agreed, disagreed or were undecided over the period of residency – the common theme was that there should be clarity for all involved: donors; their families; and healthcare professionals.

Question 8

If you answered no to the above how long, if any, should this period of residency last before they become subject to the soft opt-out system? Would this residency need to be for a continuous period?

The large majority of organisations (28, or 93%) and individuals (459, or 87%) did not answer this question.

Among those who answered the question, there was a range of alternatives suggested for the minimum period of residency, with some considering that the period was too long, others stating that it was not long enough and those who considered that there should be no time limit.

Among the 66 respondents who suggested an alternative period of residency, 40 (61%) considered that the period should be “less than one year”. Most did not suggest a specific period, but the specific suggestions made ranged from one day to six months

The predominant argument put forward by those who advocated no time limit was that as soon as someone becomes a “permanent resident” they should become subject to the soft opt-out system.

Of the remaining 26 (39%) respondents who suggested an alternative period of residency, nine suggested between one to three years, nine suggested between three to five years and eight suggested five or more years.

CCCLC considered that the law should only apply to those who have been in the country for five years or more on the basis that temporary residents [eg students and long-term visitors] may not be aware of the need to opt-out and yet would be considered as having ‘consented’ to organ donation if they fail to do so. [CCCLC, R 435]

The Christian Medical Fellowship reiterated its response to the previous question, with its preference for the opt-in system, whereby it believed that “length of residency would have no impact and where a person could donate even if they have been resident in Scotland for less than a year prior to their death”. R417 (CMF)

On whether the period of residency should be continuous, some respondents suggested that it should be, although there were some comments raised around practicalities. For example, the SCoJC (R464) agreed that residency should be continuous but were “concerned at the practicalities in terms of how new residents will be informed and medical staff will be able to determine whether a comatose patient has been resident for the required period”. SCoJC (R464)

The LSoS (R467), while considering that a year “is a reasonable period of residency”, did suggest that “there are arguments for discounting short breaks when the potential donor left Scotland for a few days” and that any issues on continuous residency of international students “could be overcome by ensuring that organisations such as Scottish universities are not able to provide information to students about how the proposed legislation may or may not affect them. Such a process could be incorporated into the admission / matriculation process. However, this will not be without difficulties for clinical staff to establish that residence criteria have been met especially when time is of the essence”. LSoS (R467)

In its response to this question, the BTS (R554) submitted—

“Rather than setting out a specific time limit it may be helpful for the Scottish Parliament to adopt the approach taken by the Welsh Act which states that the

soft opt-out system ‘will only apply to those people who live and die in Wales, who have had enough time to understand the law and have had an opportunity to opt out, if that is their wish’. To simplify the determination of residence, the Welsh Government has outlined a three-stage test which must be satisfied in practice in order for the provisions of section 4 to apply to a potential donor. The criteria are:

- Whether the person’s current address is in Wales
- Whether the person normally lives at that address for the majority of the time; and
- Whether the person has lived at that address (or another address in Wales) for at least 6 months before they died.

It is expected that use of postcodes and other rapid identifiers will be used to provide rapid verification, which will also be checked with the next of kin. If the criteria cannot be safely satisfied, consent will not be deemed to be given, although express consent from the relatives may still be sought.” BTS (R554)

Question 9

Do you think 6 months is a long enough period to run a campaign prior to change over?

Among individual respondents, 268 (50%) agreed that 6 months was sufficient time to run a suitable publicity campaign, 114 (21%) disagreed, 25 (4%) were undecided and 122 (23%) did not answer the question.

Of the organisations, three (10%) agreed, seven (23%) disagreed, three (10%) were undecided and 17 (56%) did not answer. Put another way, more than half (54%) of the organisations that answered this question disagreed.

The key theme coming out from responses, irrespective of views on the time given to any campaign, was that the campaign was appropriately focussed and presented so that the information provided absolute clarity. This ties in with the common theme from the responses: that whatever system is in place, there needs to be no room for uncertainty over rights and responsibilities.

The Royal College of Physicians of Edinburgh (R432) gave only qualified agreement:

Yes; providing this includes extensive publicity and promotion of educational information about organ donation. Improved infrastructure (including training) to support clinicians and families may take longer to put into place, however, and this **must** be prioritised in order for the introduction of a soft opt-out system to have a meaningful impact.

The British Medical Association (R429) noted that “the crucial factor is that individuals are aware of the system and know what they need to do if they wish to opt-out before it applies to them. How long this will take will depend on the frequency, nature and mode of delivery of information and education campaigns”.

A number of individual respondents (including R28, R62 and R101), who agreed that six months would be sufficient time to run a campaign, did so with the caveat that it was a suitably high profile and pro-active campaign.

Respondent 150 agreed with the campaign period, but stressed that “it’s not the time but the quality of learning and information provided. Excellent and well informed communication is essential”, while respondent 255 suggested that there could be “regular reminders” after the initial six month campaign.

Many respondents felt that the minimum time required was around a year.

Comments from respondents who offered substantive comments and reasons for believing that six months would not be sufficient time included a significant focus on the need to ensure that all residents were clear on the law:

- R431 (Church of Scotland) - We would prefer a longer campaign of up to a year, but accept that there would cost implications for this. However, every effort must be made to ensure that all citizens are aware of the implications of any change.
- R407 – For this change to succeed it is essential that the general public are well educated, trusting and supportive. It is vital that a high profile and adequately funded public relations campaign is run for at least 12 months in order to build public trust and confidence in the change. Also the process for opting-out must be highly publicised and made as simple and easy as possible. It should be possible via a number of different avenues – text, phone, on-line etc – as is the case at present with opt-in.
- R554 (British Transplantation Society) - public awareness and understanding of the opting out process is an important requirement of implementing the new law. A single 6 month campaign is unlikely to be adequate. A rolling programme of public education is far more likely to be needed to ensure long-term confidence in the general understanding about organ donation.

A number of respondents considered using the Welsh legislation as a “template”, noting that two years has been given to a suitable campaign. The CFT (R438) noted:

There needs to be a period of educational campaigns before the change-over, which should be at least a year, to 24 months. The educational campaigns should concentrate on educating the Scottish public of what the new Bill and ultimately the law will mean.

We need to observe and learn the lessons from the Welsh Government process of implementing the Human Transplantation (Wales) Act 2013 and once the Act comes into effect. CFT (R438)

The British Transplantation Society noted that “The Welsh Government’s ongoing public awareness campaign, will peak at 6 months prior to the new Act’s implementation date and continue indefinitely thereafter”.

Question 10

What is your assessment of the likely financial implications (if any) of the proposed Bill to you or your organisation? What (if any) other significant financial implications are likely to arise?

There was a distinct contrast between the responses from individuals compared to those from organisations. Individual respondents were primarily focussed on the long-term savings to the NHS. A sample of the comments submitted by individuals included:

- any financial costs would be counterbalanced by transplants reducing the burden on NHS funds. [R1]
- There will be more transplants which will mean less patients on dialysis which is a massive expense to the NHS. [R61]
- The initial set up costs will be worth the lives saved. [R73]
- increased organ donation should save money in the long term as people with new organs will be less reliant on the NHS and can return to economic activity. [R148]

Of the 14 organisations which answered this question, comments focussed on potential resource implications. For example, the British Medical Association (R429) considered that advance thought would need to be given to “the likely impact on resources of more donors becoming available, to ensure that these additional donors are able to translate into additional transplants in order to maximise the benefits arising from the new legislation”.

UK Donations Ethics Committee identified two areas of financial impact – “the necessary organisational infrastructure and the educational campaigns necessary to inform the public”. It went on to say:

Such campaigns need to cover new arrivals in Scotland and young people reaching the designated age. Where will the money come from and will spending it impede the achievement of other healthcare targets or even the intended aim of the Bill? Finally, what will be the impact on professionals of setting up and maintaining a new system in parallel with a different system in other parts of the UK. [UKDEC R 462]

Some respondents provided comparisons to the Human Transplantation (Wales) Act. The Christian Medical Fellowship (R417) argued:

The price to be paid for introducing this unnecessary (and unethical) legislation is unknown. The Welsh Government roughly estimated their set-up costs of £2.85m but failed to break these down or include on-going costs.

In 2008 a supplementary report by The Organ Donation Taskforce² estimated in far greater detail the costs of an opt-out system for the UK (based on costs

²

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122

at that time): database set-up costs (around £20m and £2m per annum in ongoing costs), IT costs (at least £10m initially and £2m per annum ongoing), communications campaign to support the opt out policy (£25m for an initial three-year campaign (**excluding** on-going communication), and healthcare training would be 'several millions'.

All this would be at the expense of other more effective measures, and in a time of challenging economic circumstances.

Not only will plans for new legislation be costly, they will be highly complicated to administer." [CMF R417]

Conversely, whilst considering that it would not be financially impacted by the proposed Bill, the BHF noted that "the benefits to be gained ... are priceless ... [and] provide favourable cost effective ratios for heart transplantation". Referring to the legislation in Wales:

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

Across all organs this would see a saving of £3million in the first year set against the costs of implementing the system change. [BHF R426]

It went on to state that one study on the increase of donation rates estimated that there could be an increase of 25-30% which would equate to approximately 15 more donors in Wales per year. It mentioned that the same study estimated that "over a ten year period ... there would be a net benefit of £2.4million per transplant [which] includes a saving of £50,000 per patient, over ten years as a result of removing the need for medical management".

A number of individual respondents suggested that any financial implications were minimal in comparison to the number of lives that could ultimately be saved (eg R141), while respondent 238 did "not consider any financial implications ... to be relevant as it is primarily an ethical question about how one should approach organ donation rather than an economic argument".

The Church of Scotland captured these sentiments by submitting:

- It is important, in considering changes to the law, that ethical issues be taken into account, and that financial implications not be the primary driver of our decisions. A person's wishes as to whether or not to donate their tissues or organs for transplantation must be paramount. [Church of Scotland, R431]

Question 11

Is the proposed Bill likely to have any substantial positive or negative implications for equality? If it is likely to have substantial negative implication, how might this be minimised or avoided?

69 (13%) of individual respondents believed the proposed bill would have positive implications for equality, 62 (11%) believed the implications would be substantially negative. Just under a quarter (129) answered the implications would be neither positive or negative, 37 (7%) were undecided and 233 (44%) did not answer the question.

,Two organisations thought it would have positive implications, 10 (30%) felt the implications would be negative. 12 (40%) organisations did not answer the question and the remaining 6 (20%) were either undecided or considered that the proposed Bill would have neither positive nor negative implications.

The Catholic Parliamentary Office (R414) considered that the proposal was “intrinsically discriminatory in that it denies the integrity of the person by overriding the requirement for consent on how a person’s organs may be used” and that the proposal sought to “establish a principle in law that the consent of the person can be determined by the authority of the state”. It concluded that “such an arbitrary determination ... puts citizens at risk of arbitrary and discriminatory choices”.

A number of respondents identified a potential negative impact on “hard to reach” groups, faith groups and the BME community. For example, Revival (R252), who are generally supportive of the proposal noted that “it would be important to have the views of various Faith Groups and Equalities Groups before proceeding” and suggested that the views from these groups could persuade it to change its position.

The BHF did not identify any negative equality issues, noting that the proposed Bill “only seeks to change the method in which you register as a donor. The soft opt out system will protect cultural objections to organ donation through the retention of the family’s role after death”. It raised a particular point in relation to BME communities, saying that “research has shown that the most common barrier to organ donation in BME communities is lack of information”, highlighting the need to ensure that the awareness raising campaign catered for all sections of society.

The FCS (R416) felt that “disadvantaged groups and ethnic minorities are more liable to be affected, because they would be more difficult to inform adequately about changes in the law”.

UK Donations Ethics Committee noted that “one of the main barriers to family consent is faith and cultural concerns, specifically among the BME community” and suggested that “structured and meaningful engagement with faith communities is necessary in order to ensure appropriate understanding of the policy changes proposed”.

Children in Scotland (R430) did not directly address this question but did stress the importance of considering children’s rights. For example, they suggested that “a full Child Rights Impact Assessment (CRIA) of the Bill be completed”. They highlighted the recommendations from the CRIA carried out for implementation of the soft opt-out system in Wales, which included the importance of:

- Ensuring that any public awareness raising campaigns include work with schools and in other ways actively engaging with children and young people.
- Ensuring that systems storing personal details and preferences are secure and that information is held confidentially. This acknowledges the UNCRC Article 6 about children’s right to privacy.
- Ensuring that public awareness campaigns take account of the specific needs of disabled children.

Again identifying the importance of the publicity campaign, the Scottish Youth Parliament believed that “the Bill will have positive implications for equality, providing that children and young people are informed about the change from an opt-in system to a soft opt-out system”.

The GMC, whilst not expressly stating its position submitted:

- In considering the implications for equality, it may be helpful to think about whether and how information about donation and transplantation can reach all members of our society. If it doesn’t do so, those already disadvantaged in the healthcare system (those with poor literacy, people with no functional use of English, people with learning difficulties etc.), are likely to experience further inequality.[GMC, R 556]

Question 12

Do you have any other comments on or suggestions relevant to the proposal?

Additional comments or suggestions were provided by 118 (22%) individual respondents and 21 (70%) organisations.

UK Donations Ethics Committee [R 462] identified what it considered to be potential “unintended consequences” stating:

- ... the justification for intervening, and the balance of benefits and burdens that need to be weighed up in deciding whether an intervention is for the benefit of the patient, relies heavily on the strength of evidence that the patient wants to be an organ donor. There are many clinical decisions to be made and the strength of authorisation/consent, and the support for donation of the family, is vital to making decisions as to which measures are to the benefit of the patient. We feel that there is a risk of over-reliance on any form of consent to donation after death when making decisions about interventions during life.

UKDEC recognises that there will still be an “opt in” register under the proposals, but we are concerned that a shift towards reliance on the absence of opting out as the basis of consent to donation could shift the delicate balance and undermine professionals’ confidence to develop the innovative schemes that have the potential to increase the number of organs for transplantation.

Were this to happen and the unintended consequence limited new opportunities for increasing available organs, this would work against the

overall aim of the proposal.. We would recommend further work be undertaken on the potential impact on clinical practice in this area. UKDEC [R 462)

LSoS [R 467] raised a number of additional points around the following areas:

- education and training – suggesting that this was vital, particularly for “those involved in health care, assessment of capacity or proxy decision making”.
- research – “Research should be encouraged to gauge acceptability and feasibility of any new legislation”.
- patient or potential donor – noting that the public would “need to be reassured that a clear separation exists between the treatment and transplantation and the respective roles of those involved” to alleviate any concerns that “clinicians will not strive to save life”
- process – “any database or process adopted should be effective, up to date and accessible” and should also “provide an option should an individual choose to exercise a preference over which organs should or should not be removed”. This was a view echoed by the Free Church of Scotland (R416), the Church of Scotland (R431) and the Scottish Council of Jewish Communities (R464)
- the suitability of organs (in a circumstance in which an individual has self-administered a drug designed “to ensure a rapid death”) – “Where the deceased person has self-administered such a drug, their organs may be unsuitable for transplantation purposes as they may have become tainted through the absorption of that drug into their bodily systems”.
- advancement of medical science – “We note that through the advancement of medical research and technology, the scope of transplantation of both organ and other body parts is rapidly evolving. We suggest that any proposed Bill has enabling provisions to take into account those advances”.

The Royal College of Physicians and Surgeons of Glasgow (RCPSG) (R534) argued that:

The current informed consent system has been substantially improved over the last five years by means of better co-ordination. These changes have resulted in a 50% increase in the number of deceased organ donors over that period.⁶ It is important that such a level of donation is maintained and increased over time in order to further reduce the organ supply deficit. The Organ Donation Taskforce in its plan for 2013-2020 outlines the continued introduction of organisational changes to increase rates of donation, with added emphasis on information technology systems. [Royal College of Physicians and Surgeons of Glasgow (RCPSG) R534]

It summarised its view by saying that “Overall there does not seem to be sufficient compelling evidence of the benefits of a change to a system of presumed consent to justify endangering the current system”, which was a view also raised by the Scottish Council of Jewish Communities (R464).

CCCLC strongly opposed the proposal, saying “It represents a fundamental ethical shift, does not involve consent and fails to protect the fundamental dignity of every

human being. An increase in donations can be achieved by diverting resources to other more effective measures". [CCCLC R435]

The CFT confirmed its support for the proposal but added that it was "aware that legislation alone will not be enough to significantly improve transplantation rates" and hoped that the proposal would lead to "a much needed discussion of organ transplantation, ultimately leading to increased donation rates across the whole of the UK". [CFT R438]

Revival (R252), who supported the proposal added that "it would be essential that all potential donors and their families continue to see organ donation as a gift". The same view was expressed by the Surgical Intensive Care Unit (R415), although they were against the proposal.

The BMA submitted that "careful consideration needs to be given to the position regarding patients who lack capacity", adding that "the important factor is whether the individual has had capacity for a sufficient period since the legislation was passed to know and understand its provisions and to take steps to opt-out if that is his or her wish". For consistency it suggested that the period of capacity could be the same as the period of residency. [BMA R429]

SECTION 4: SECTION 4: COMMENTARY BY ANNE MCTAGGART MSP

I would like to take the opportunity first of all to thank everyone who took the time to engage in the consultation on my proposed Organ and Tissue Donation (Scotland) Bill. The response rate from individual members of the public and interested organisations was great to see.

I wish to also express my thanks to the Non-Government Bills Unit (NGBU) for their assistance and all those who took time to support the proposal to this date.

I took the decision in 2014 to drive this Bill forward because I believe that people are needlessly dying in Scotland and across the UK, due to a lack of organs available for transplant. The Scottish Government and partners should be commended for their efforts to raise awareness of organ donation and to increase the number of people on the organ donor register. However, the pace of change is too slow and the truth is that three people a day die in the UK who are in need of a transplant.

The aim of my consultation was to provide an opportunity to receive views and comment as well as analysis and to gauge public opinion. It was an opportunity to enable people and organisations to argue the case for certain refinements. In both respects, I believe that this has been an extremely successful consultation.

I am heartened to see that 80%, a significant majority, of individuals who responded supported the Bill and over half of the respondents felt that legislation was essential.

I also note those who have used this opportunity to voice their opposition. Whilst a number of organisations (12) opposed the proposals, 11 supported the legislation. Amongst those organisations opposing the proposals or undecided, some suggested that we wait and see how the legislation works in Wales.

The Welsh Government will introduce a soft-opt out system in Wales on 1 December 2015. Whilst the position to wait and see may be appealing to many, we would have to wait until at least 2020 before any post-legislative scrutiny could take place, meaning it would most likely be 2022 before any legislation was introduced in Scotland. In the meantime, approximately 7,500 people across the UK will have lost their life due to lack of organs.

Soft-opt out is not a new method for recording peoples wishes on organ donation. It has been used across Europe since as early as the 1950s, and is currently used in Norway, Belgium, Sweden, France, Croatia, Brazil, Chile to name a few. We have an opportunity to analyse and study the practices of these countries much sooner than Wales.

In Scotland only 5% of the population oppose transplantation in principle³ and in fact over 90% of Scottish people support organ donation⁴. Nevertheless, only 40% of the population is on the organ donor register. A significant proportion of people in Scotland, therefore, would wish to donate their organs after death for the purpose of transplantation but (for whatever reason) have not registered as a donor. I believe this serves as powerful evidence to propose reform of the current organ donation system.

³ <http://www.scotland.gov.uk/Publications/2013/07/7461/2>

⁴ <http://bma.org.uk/working-for-change/improving-and-protecting-health/organ-donation/scotland>

Whilst working on this Bill and during the consultation period, I have had the opportunity to meet with some of the lucky people who have had a second chance through organ transplant. Their lives have been transformed and their opportunities for a new tomorrow given back to them. There are too many people dying needlessly due to the lack of organs available for transplant.

Soft-opt out does not change the options available for the Scottish public, in fact it gives them a stronger voice by, for the first time, being able to register their clear objections to donation therefore supporting families to make the right decision during a time that is understandably traumatic for them.

The overwhelming support by individuals, the experiences that have been related to me during the consultation period and the conversations I have had with both supportive and non-supportive organisations have affirmed to me that it is right that the Scottish Parliament has this conversation in an open and transparent way and that is why I propose to continue my work on this Bill and seek to introduce legislation before the end of this Parliamentary session.

ANNEXE A: ORGANISATIONAL RESPONDENTS, NUMBERED AS RECEIVED

Proposed Organ Donation (Scotland) Bill

Lists of organisations that responded to the consultation

Numerical list

Response number	Name of organisation
168	Scottish Churches Parliamentary Office
252	Revival
253	Royal College of Surgeons of Edinburgh
414	Catholic Parliamentary Office
415	Surgical Intensive Care Unit
416	Free Church of Scotland
417	Christian Medical Fellowship
421	Milton Community Council
426	British Heart Foundation
427	Scottish Youth Parliament
429	British Medical Association
430	Children in Scotland
431	The Church of Scotland
432	Royal College of Physicians
434	Kidney Research UK
435	Christian Concern & Christian Legal Centre
436	NHS Blood and Transplant
437	Scottish Council on Human Bioethics
438	Cystic Fibrosis Trust
439	Scottish Episcopal Church
462	UK Donation Ethics Committee
463	CARE for Scotland
464	Scottish Council of Jewish Communities
465	NHS Forth Valley
467	The Law Society of Scotland
534	Royal College of Physicians and Surgeons in Glasgow
554	British Transplantation Society
555	Royal College of Nursing
556	General Medical Council
557	Free Church of Scotland (Continuing)

ANNEXE B

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