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Organ and Tissue Donation and Transplantation: Analysis of Responses



HEALTH AND SOCIAL CARE



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Abbreviations

Note that throughout this report, the following abbreviations will be used:

ODR – Organ Donor Register

SNOD – Specialist Nurse for Organ Donation

Definitions

The following terms are used throughout this report to refer to organ and tissue donation systems:

Opt in: In this system, a person must either express a wish to donate their organs or tissue, or a relative can authorise donation on their behalf. This is the current system in Scotland.

Opt out: In this system, organs and tissue can be taken for transplantation unless a person has made it clear they do not wish this to happen after their death. This type of system is also known as **deemed authorisation**.

Soft opt out: This system builds on deemed authorisation, but also incorporates additional safeguards and conditions which might include seeking authorisation from the person's nearest relative, for certain groups of people, or in certain circumstances.

Executive summary

Introduction

1. Between 7 December 2016 and 14 March 2017, the Scottish Government undertook a public consultation inviting views on ways of increasing the numbers of successful organ and tissue donations. The consultation paper outlined current procedures regarding organ and tissue donation, and options for increasing donations including, potentially, the introduction of an opt out / deemed authorisation system (i.e. where organs and tissue can be taken for transplantation unless people have made it clear they do not wish this to happen after their death). It also suggested possible ways of increasing referrals by clinical teams to specialist transplant teams when they are caring for a dying or recently deceased patient.
2. The consultation paper was made available on the Scottish Government's online consultation hub and was also sent directly to relevant stakeholder groups.
3. The consultation contained 18 questions which were a mix of closed (tick-box) questions and open questions inviting further comment. Both quantitative and qualitative analyses of the responses were undertaken. The aim of the analysis was to report on responses to the consultation's closed questions, and explore the reasons respondents gave for their answers, highlighting differences in views between different groups where appropriate. However, it should be noted that not all respondents answered all questions. Some organisational respondents, in particular, chose not to answer the closed (tick-box) questions, but provided comments on issues relevant to the question.
4. The findings presented here summarise the views of those who participated in the consultation. Given that this was a self-selected group, these findings should not be seen as representing the views of the wider population.

About the respondents

5. The consultation received 824 responses from 778 individuals and 45 organisations. In addition, one response took the form of a petition with 18,500 signatures. Organisational respondents comprised NHS and local authority bodies (including partnerships); voluntary sector agencies and charities; professional and regulatory bodies; and faith groups.

Respondents' views on the principle of a soft opt out system (Q1)

6. Most individuals (84%) supported the principle of a soft opt out system (that is, an opt out system with additional checks built in), while organisations were divided in their views (53% in favour vs 47% opposed). Among organisations, voluntary sector groups were largely in support of the principle of a soft opt out system while faith groups were mainly opposed.

Views on improving the current opt in system (Q2)

7. Respondents were also asked for their views about changes which might be made to the current opt in system to increase the number of organs available for transplant. A wide range of suggestions were offered. These focused on: respecting donors' wishes; developing initiatives within the health service to increase donations; taking active steps to encourage registration on the Organ Donor Register (ODR); promoting and advertising organ donation; and improving information on organ donation and transplantation. Respondents also discussed potential administrative improvements to the current system.
8. At the same time, however, some respondents thought the current system already worked well, while others thought it could not be made to work well.

Taking account of the views of family members where an individual has opted in (Q3)

9. The consultation asked for views on whether a donation should or should not proceed in a situation where families oppose a donation even though the individual has indicated their wishes to be an organ donor.

10. Most individual respondents (83%) were in favour of the donation proceeding in these circumstances, while most organisations (64%) thought that the donation should not proceed.

11. Respondents who were in favour of the donation proceeding despite family objections argued that families did not have the 'right' to overrule a decision taken by a potential donor, nor were they well placed to make such a decision at the time of a loved one's death.

12. Those who thought that the donation should not go ahead if the family opposed it believed that proceeding in such circumstances would: (i) exacerbate family distress; (ii) alienate families; (iii) undermine public confidence in the health service and organ donation system; and (iv) endanger patient safety. However, within this group there was also a view that decisions in such circumstances should be taken on a case by case basis, and that sensitive efforts should be made to encourage the family to respect the donor's wishes.

Operation of a soft opt out system (Q4)

13. The consultation paper explained that a workable soft opt out system would involve: (i) high profile awareness-raising campaigns for at least 12 months before the introduction of the new system, and on a regular basis after implementation; and (ii) upon the death of an individual in hospital, a process of undertaking a range of checks to decide whether a donation from that individual could proceed. The consultation asked for views in relation to the proposed checks.

14. In general, respondents agreed that, if an opt out system were introduced, the proposed checks set out in the consultation paper were sufficient to decide whether the donation should proceed. Two-thirds (67%) of organisational respondents and 86% of individual respondents indicated agreement. However, four out of the six faith groups thought the checks outlined were not sufficient.

15. Those who did not think the checks were sufficient were generally opposed to the principle of an opt out system and concerned about the practice of deemed authorisation. Occasionally, this group of respondents suggested additional checks that could be included and many of these focused on a situation in which an individual's family / friends were unable to be contacted or identified.

Decision-making in an opt out system where a donation may distress the donor's family (Q5)

16. Most organisational respondents (72%) thought that if a deemed authorisation donation was likely to distress the potential donor's family, then the donation should not proceed. There were divided views on this question among charities and voluntary sector groups.

17. A small majority of individual respondents (57%) were in favour of the donation proceeding in this situation. However, the level of support for proceeding in a deemed authorisation situation was not as great as it was for the situation described above, where the donor had explicitly opted in to the ODR. (See discussion of Question 3 above).

18. While some respondents were strongly against families being able to overrule decisions (deemed or otherwise), others prioritised the wishes of the family. Among this latter group, the risk of causing distress, and concerns about possible perceived pressure on families to agree were seen as key reasons for not supporting an opt out system.

Requirement for explicit authorisation in a soft opt out system (Q6 – Q9)

19. The consultation paper explained that in a soft opt out system, where deemed authorisation would generally apply, there could also be 'excepted' categories of people – for whom explicit authorisation would continue to be required. Three excepted categories were proposed: (i) adults with incapacity; (ii) children under a certain age; and (iii) anyone who had been resident in Scotland for less than 12 months.

20. Most respondents (73% of organisations and 79% of individuals) agreed with the three excepted categories. Only faith groups among the organisational respondents were more likely to say that the three categories would not be sufficient in a soft opt out system. Respondents who thought the categories were not sufficient were generally opposed in principle to a soft opt out system. However, some respondents highlighted concerns in relation to one or more of the proposed excepted categories (most often, in relation to people resident in Scotland for less than 12 months), or they suggested a small number of other groups for whom explicit authorisation should be required.

21. Separate questions were included in the consultation to explore: (i) the circumstances in which an adult should be viewed as not having the capacity to make their own decisions about donation; (ii) the age at which deemed authorisation provisions would apply for children; and (iii) whether local authorities should be able to authorise donation following the death of a child in care, if no parent is available.

- **Adults with incapacity:** Respondents thought that the Adults with Incapacity (Scotland) Act 2000 should provide the basis for guidance regarding capacity. However, some wanted clarification about the timeframe for this provision, and how it might take account of cases where a person's capacity changed over time.
- **Age threshold for deemed authorisation provisions in children:** The largest proportion of both organisational and individual respondents thought that explicit authorisation should be required for all children under 16, and that deemed authorisation should apply for young people aged 16 and over. Around half of organisations (52%) and two-fifths (42%) of individuals expressed this view. However, comments indicated that respondents may have interpreted the question in different ways and therefore these findings should be treated with caution.
- **Children in care:** The largest proportion of both organisational and individual respondents thought that local authorities should be able to authorise donations where a child dies while in care, if no parent is available (46% of organisations and 57% of individuals said this). However, organisations were more likely to say 'no' or 'don't know' in response to this question.

Donations of less common types of organs or tissue (Q10)

22. Just under half of organisations (46%) were in favour of deemed authorisation provisions applying to all – and not just the most common – organs and tissue. By contrast, 83% of individuals were in favour of this.

Pre-death tests and treatment for potential donors (Q11 – Q13)

23. Most respondents agreed that clinicians should be able to carry out a range of medical tests on a potential donor before life-sustaining treatment was withdrawn.

24. Among those who disagreed, just over half thought that the tests could be permitted if the person had previously made it clear that they wished to be a donor. A fifth thought the

tests could be permitted if the family provided consent. Just under a third thought such tests should never be permitted.

25. In addition, a majority of respondents (67% of organisations and 72% of individuals) agreed that, where a patient's condition is unsurvivable and it will not cause them discomfort, it should be permitted to administer medication to the patient before their death to improve the chances of a successful transplantation. Respondents who opposed this proposal expressed concerns about carrying out treatment on one person for the benefit of another.

Involvement of authorised representatives (Q14)

26. There were different views among organisations and individuals about whether people should have the option to appoint one or more authorised representatives to make decisions for them about donation before they die. A small majority of organisations (52%) said that this was not necessary, while a small majority of individuals (53%) said that this type of proxy authorisation should be allowed.

27. While some respondents thought that proxy authorisation could be useful in certain circumstances, others argued that individuals could simply make their wishes known by opting in or out of the ODR.

Health service initiatives to increase the number donors (Q16 and Q17)

28. A large majority of respondents (81% of organisations and 88% of individuals) thought that the Chief Medical Officer (CMO) should issue guidance to clinicians to refer almost all dying or recently deceased patients for consideration as potential organ or tissue donors. Respondents thought that CMO guidance would support good practice in involving specialist staff, and help raise awareness across the healthcare workforce. However, there were also concerns about the need to focus on appropriate cases and maintain the current ethos of the organ donation system, and the need to consider resource implications.

29. There was also strong support for the proposal to require specialist staff to be involved in discussions with families about organ donation (81% of organisations and 78% of individuals were in favour). Respondents thought that involving specialist staff in such discussions would increase the chances of authorisation being granted, and would have a positive impact on the wellbeing of families. However, potential resource implications were also noted, and there was also a view that the absence of specialist staff should not prevent discussions with families about organ donation. Those who did not support the proposal did not see it as necessary or were concerned about the resource implications, or about ethics.

Equalities impacts and implications (Q18)

30. Just over half of organisations (55%) and around a fifth of individuals (18%) said they could identify impacts or implications for particular equalities groups. Respondents identified possible negative impacts for: those opposed to organ donation including those opposed for religious or cultural reasons; and various vulnerable, hard-to-reach and socially disadvantaged groups. Respondents identified positive impacts for black and ethnic minority groups, and for people with disabilities and long term health conditions, both of whom it was suggested would benefit from an increased supply of suitable organs for transplantation.

Other comments (Q15)

31. Respondents highlighted a range of issues to be considered if a soft opt out system were introduced. They also highlighted the importance of continuing with initiatives to increase successful organ and tissue donations regardless of the system in place.

1. Introduction and background

1.1 Between 7 December 2016 and 14 March 2017, the Scottish Government undertook a public consultation to invite views about possible ways of increasing the numbers of successful organ and tissue donations.¹ This report presents the findings from an analysis of the responses to the consultation.

Policy context

1.2 Organ and tissue transplants can save people's lives and / or substantially improve their health and quality of life. Although Scotland has the highest proportion of people registered as organ donors in the UK (45%), there is still a shortage of organs, and around 500 people are waiting for a transplant at any one point. The Scottish Government is keen to explore ways of increasing the number of organs and tissue available for transplantation, particularly given that fewer than 1% of deaths in Scotland occur in circumstances where the person is able to donate their organs.

1.3 At present, in Scotland, in order to become an organ or tissue donor, a person must either express a wish to do so or one of their relatives can authorise donation on their behalf. This system is known as '**opt in**'. In many cases, individuals make their wishes known by joining the NHS Organ Donor Register (ODR). If an individual has not given authorisation and they could be a potential organ donor, their nearest relative will be asked to make a decision in the event of the individual's death. Having such sensitive conversations with families at the time an individual dies is very difficult, and, understandably, many families find it impossible to consider such requests with the urgency required at a time when they may be in shock or grieving. In such circumstances a significant minority of families (37% in 2016-17) do not give authorisation, although survey evidence suggests that the majority of people in Scotland support donation.²

1.4 Additionally, timely referral to a specialist nurse for organ donation (SNOD) or a tissue donor coordinator by the clinical team caring for a potential donor is an important step in allowing a donation to proceed, as it allows specialist transplant staff to assess the suitability of the patient for becoming an organ or tissue donor, and to be involved in discussions with the patient's nearest relative. Research shows, however, that this does not always happen. Potential donors are not referred by the clinical team for a variety of reasons, and specialist staff are not always involved in discussions with families.

1.5 Thus increasing the number of people authorising donation, and increasing the number of referrals of potential donors by medical teams are both important way of maximising the number of organs and tissues available for donation. The current consultation explores how this might be done, and invites views on two main approaches which might be used to increase the number of successful deceased organ and tissue donations:

- **By increasing the number of potential donors**, primarily by introducing a system whereby a person is regarded as having authorised donation, unless they have expressed a wish **not** to be a donor – this is called a 'deemed authorisation', or 'opt out' system. A **soft opt out system** builds on deemed authorisation, but also

¹ <https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/>.

² In a survey of 1032 people in Scotland carried out by TNS in August 2016, 70% of people agreed that 'we should all register to be organ donors'.

incorporates additional safeguards and conditions which might include seeking authorisation from a person's nearest relative. Such a system has recently been introduced in Wales, where the Human Transplantation (Wales) Act 2013 came into effect on 1 December 2015. The consultation paper makes it clear that the Scottish Government is willing to consider a soft opt out system if this can be developed in a way which will not harm trust in the NHS or the safety of transplantation, but it also invites views on ways that the current opt in system might be made more effective.

- **By increasing the number of potential donors referred to a SNOD or a tissue donor coordinator.** The consultation recognises the importance of this step in the process and proposes two ways of increasing such referrals: (i) by the issuing of Chief Medical Officer (CMO) guidance to encourage clinicians to refer dying or recently deceased patients for consideration as organ and / or tissue donors, and (ii) by making it a requirement to involve a specialist nurse or other individual with appropriate training in discussions with families about authorising donation.

The consultation

1.6 The consultation paper outlined current procedures regarding organ and tissue donation, and the options which might be considered in order to increase donations. The consultation paper was split into two sections. Section 1 considered ways of increasing potential donors, and had a particular focus on the option of a soft opt out system. Section 2 considered ways of increasing referrals by clinical teams to specialist transplant teams when they are caring for a dying or recently deceased patient. The consultation contained 18 questions (including 5 multi-part questions) which were a mix of closed (tick-box) questions and open questions asking respondents to provide written comment. Questions 1 to 15 asked for views on options for increasing potential donors, and Questions 16 and 17 asked for views on increasing referrals to specialist transplant teams. A final question, Question 18, asked for views on equality issues.

1.7 The consultation was launched by the Minister for Public Health and Sport on 7 December 2016. It was made available on the Scottish Government's online consultation hub, and was also sent to over 260 stakeholder groups. Respondents were able to respond to the consultation online or they could submit written responses by email or post.

About the analysis

1.8 Both quantitative and qualitative analyses of the responses were undertaken, with the emphasis on the latter. Frequency analysis was carried out in relation to all the closed questions and the results of this are presented in tables throughout the report. In relation to the qualitative analysis, analytical frameworks were developed for each of the questions. The focus of analysis was on identifying areas of agreement and disagreement between different groups of respondents, and the main themes and the full range of views submitted in response to each of the consultation questions. If respondents held different views in relation to a particular closed question, wherever possible, the **reasons** given for those different views were further explored in the qualitative analysis.

1.9 Not all respondents answered all questions, and some made comments in relation to a question without ticking a response at the relevant closed question. Where a respondent's answer to a closed question was clear from the comments they made, the response to the closed question has been imputed and included in the quantitative tables. Irrespective of

whether it was possible to impute a response to the closed question, all respondents' comments were included in the qualitative analysis.

1.10 This report aims to provide a balanced account of the views submitted by respondents. However, the findings only provide a relatively high-level summary of a range of more detailed responses. Furthermore, given that those who took part in the consultation were self-selecting, the findings should not be taken as representing the views of the wider population.

About the report

1.11 This report contains 13 chapters. Chapter 2 describes the respondents and the responses received. Chapters 3 to 13 present the findings of the analysis for each of the consultation questions. Annexes to the report contain a list of organisational respondents to the consultation, and details of the number of responses to each question.

2. Responses and respondents

2.1 This chapter presents information about the respondents and types of responses received in the consultation.

The responses

2.2 Altogether, 836 responses were received to the consultation. One response to the consultation took the form of a petition with 18,500 signatures. The text of this petition has been included in the analysis as a single response.³ Twelve respondents submitted two responses – these multiple responses were amalgamated into a single composite response for each of these respondents. Thus the analysis presented in this report is based on **824 responses**.

The respondents

2.3 Respondents were asked to specify whether they were submitting their response as an individual, or on behalf of an organisation or group. The vast majority of respondents were individuals (n=778; 94%). (See Table 2.1.)

Table 2.1: Types of respondent

Respondent type	n	%
Individual	778	94%
Organisation	45	5%
Petition	1	0%
Total	824	100%

* Percentages do not total 100% due to rounding.

2.4 Table 2.2 below provides further detail about the organisational respondents.

Table 2.2: Organisational respondents

Organisation type	n	%
NHS and / or local authority organisations	14	31%
Professional groups and regulatory bodies	12	27%
Charity, voluntary sector or patients' rights groups	11	24%
Faith groups	8	18%
Total	45	100%

2.5 The largest group of organisational respondents were NHS and local authority organisations, accounting for almost a third of organisations (31%; 14 out of 45). Organisational respondents also included: (i) professional (medical, scientific and legal) organisations and regulatory bodies of various types; (ii) charities and voluntary sector organisations (mainly those operating in the health field with remits including fundraising,

³ The petition was submitted by 38 Degrees and was noted as being a response to Question 1: What do you think of the principle of a soft opt out system for Scotland? The full text of the petition read: 'Put everyone on the organ donor register automatically – with the option to opt out'. The petition text is included in the analysis of responses to Question 1 in Chapter 3 of this report.

research, information provision and patient support and representation); and (iii) faith groups. A complete list of the 45 organisational / group respondents is shown in Annex 1 of this report.

Response rates

2.6 As noted in Chapter 1, not all respondents answered all the consultation questions. Response rates were higher for the closed questions, and most of these were completed by over 94% of respondents. Response rates for open questions were lower, ranging from 74% (for Question 7) to 8% (for Question 12). Note, however, that some questions (including Question 12) were intended to be answered by only a sub-group of respondents. Specifically, respondents who answered a closed question in a particular way were, in some cases, asked for further information about their views. Thus, the response rates for these types of follow-up questions are lower than for other open questions in the questionnaire.

2.7 Annex 2 of this report provides further details about the response rates for each of the consultation questions.

3. Views on a soft opt out system (Q1)

3.1 Chapter 1 of the consultation paper considered ways to increase authorisation for organ and tissue donation. One option considered is that of a soft opt out system. In such a system individuals are deemed to have agreed to being an organ or tissue donor unless they have indicated that they do not wish to donate, but family members are nevertheless asked if they were aware of the patient having expressed any objections to donating before the donation proceeds. Although the consultation paper states that there are other options available – including retention or reform of the current opt in system – much of the chapter is devoted to exploring various issues related to the possible introduction and operation of a soft opt out system in Scotland.

3.2 Question 1, a tick-box question, asked respondents for their views on the principle of a soft opt out system:

Question 1: What do you think of the principle of a soft opt out system for Scotland? [I support the principle of a soft opt out system in Scotland / I do not support the principle of a soft opt out system]

3.3 A total of 801 respondents – 771 individuals and 30 organisations – answered Question 1. Table 3.1 shows that there was a clear difference in the views of individuals and organisations. A majority of individuals (more than four-fifths) supported the principle of a soft opt out system, while organisational respondents were divided in their views (16 supported the principle while 14 did not). However, among the organisational respondents, charities and other voluntary sector groups were largely in favour, while faith groups were mainly opposed.

Table 3.1 – Question 1: What do you think of the principle of a soft opt out system for Scotland?

Respondent type	Supports principle	Does not support principle	Total
NHS and / or local authority	4	5	9
Charity, voluntary sector or patients' rights groups	8	1	9
Professional groups and regulatory bodies	3	3	6
Faith groups	1	5	6
Organisation total	16	14	30
Organisation percentage	53%	47%	100%
Individual respondents	644	127	771
Individual percentage	84%	16%	100%
Total (organisations and individuals)	660	141	801
Total percentage	82%	18%	100%

3.4 The consultation questionnaire did not include space for respondents to provide additional comment. It was, however, common for respondents to expand on the reasons for

their answer,⁴ and the sections below present an analysis of the views of those who supported and those who did not support the principle of a soft opt out system.

3.5 There are several points which should be noted about the analysis:

- More than a quarter of organisations provided comment relevant to the question (e.g. on overall attitudes to organ donation, or the pros and cons of different approaches) without indicating clear support for or opposition to an opt out system – this included representative bodies who reported that there was no consensus amongst their membership on this issue, and organisations that indicated that their remit precluded them from offering a policy view. The views of this group are not presented separately, as the points they made reflected the points made by other respondents.
- Most individuals provided brief comments only, whilst organisations provided lengthier and more detailed responses. Furthermore, individuals tended to offer a single reason for their support or opposition to a soft opt out system while organisations provided more in-depth responses, covering multiple, linked points and recognising advantages and disadvantages of different approaches. However, the basic points made across both groups were often similar in nature.
- Among both groups (i.e. those supporting and those not supporting a soft opt out) there were respondents who identified themselves as having a personal interest in this issue – they or a family member had received or were waiting for a transplant, they had experience of a family member becoming a donor, or had professional experience of organ donation and transplantation.

3.6 In addition, some respondents said that the exact nature of the opt out system being proposed by the Scottish Government was not clear, or the comments made suggested respondents may have interpreted the concept differently, e.g. some may have been talking about a hard rather than soft opt out system; in other cases, it was not clear what type of system respondents were referring to.

3.7 With few exceptions, respondents indicated support for organ donation and transplantation in general. They were positive about the benefits transplantation could bring to those in need in term of saving lives and enhancing quality of life, but also saw organ and tissue donation as a positive and powerful act in itself which allowed one human to help another. For some, an opt out system was seen as a way of further enabling this process; for others such a system risked undermining what they saw as the essential altruistic nature of the donation.

Views of those who supported the principle of a soft opt out system

3.8 Those who supported the principle of a soft opt out system for Scotland offered the following main reasons focusing on efficacy, evidence and ethical considerations:

- They did not think the current opt in system was working, and did not think an opt in system could be made to work sufficiently well. They thought an opt out system provided the most effective way of increasing the number of donors.

⁴ Respondents who submitted offline responses were able to provide comment immediately at Question 1, while those completing the online questionnaire generally expanded on their answer at Question 2 or Question 15.

- They thought that the available evidence, including emerging evidence on the Welsh opt out system, indicated the effectiveness of opt out systems – organisations were particularly likely to offer this view. They also argued that such a system was supported by public opinion.
- They thought an opt out system was justifiable on ethical grounds, suggesting that such a system respected the rights of individuals, in that everyone had a choice, and those not wishing to donate would be motivated to opt out. They also noted that most people would accept an organ if they or a family member were in need of a transplant, and that society as a whole would benefit from such a system.

3.9 Additionally, respondents identified a number of more specific advantages or benefits which would result from a soft opt out system, such as:

- Encouraging discussion within society as a whole and within families, and helping change attitudes to make organ donation the ‘norm’
- Addressing the problem of people not getting around to opting in
- Making the job of approaching families easier for healthcare staff, and making donation authorisation decisions easier for families, if donation was seen as the default position.

3.10 However, respondents – organisations in particular – also offered a range of caveats and qualifications to their support. Most commonly they emphasised:

- The need for appropriate safeguards, and the importance of support for families and respect for their views
- The importance of any new opt out system being introduced as part of a broad strategy which would involve appropriate publicity and information, health service infrastructure, staffing and staff training, etc.

Views of those who did not support the principle of a soft opt out

3.11 The views of those who did **not** support the principle of a soft opt out system also focused on issues of efficacy, evidence, and ethics, but practical concerns also featured strongly in the comments made. The main themes in the comment are as summarised below:

- Respondents thought the current system worked effectively – they highlighted in particular that donations had been increasing over recent years as a result of ongoing initiatives, and thought that there was scope to continue with this work and improve donation rates further.
- They did not think that a move to an opt out system was supported by the available evidence. They argued that international evidence on the impact of opt out systems on donation rates was mixed, and indicated that a range of factors, rather than just the type of donor system in place, contributed to donation rates. As such, respondents thought that there were other initiatives which could be pursued in order to increase donations. They also queried whether enough was known about public awareness, attitudes and behaviours in Scotland and elsewhere in relation to different systems.
- They had moral or ethical concerns about the principles underpinning a soft opt out system. Respondents thought that organ donation should always require explicit,

conscious authorisation, with no implied obligation. It was further suggested that an opt out system removed the right to choose whether or not to be an organ donor from those who had not considered the matter. Respondents highlighted the importance of organs being donated freely, as a 'gift', and thought that anything that detracted from this principle was damaging to human dignity and society; raised issues about the relationship between the state and the individual and ownership of the human body; and risked the commodification of human beings. Those with concerns based on religious beliefs attached particular importance to the need to protect human autonomy and the sanctity of the human body or noted that some religious groups were opposed to organ donation under any system. Respondents also highlighted a number of perceived risks which they felt raised ethical issues: (i) the risk of donation decisions being made which were not in line with the wishes of the individual – e.g. where an individual had not taken action to opt out and their family did not know their wishes; (ii) the risk of mistakes being made as a result of administrative errors; (iii) the risk of the system being abused by medics, or of families being pressurised in pursuit of the 'greater good'. Those offering views of this type included a few individuals who personally did not wish to be organ donors; no organisation indicated an opposition to donation per se.

- Respondents also had **practical** concerns about how a soft opt out system would operate. They thought such a system would be expensive and difficult to administer for the NHS, and thought it would detract from other ways of increasing organ donations, or from developments which might reduce the need for transplants. Some queried whether priority should be given to this matter at a time when the health service was under increasing pressure. Respondents also thought the system would be difficult for the public to understand and would rely too much on people taking action to opt out and to update their wishes as necessary. There was also a concern that an opt out system might be counter-productive, in that it could: (i) lead to an increase in the numbers opting out⁵ and the rate of family refusal if the person's nearest relatives were not confident about the wishes of the individual; and (ii) erode trust in healthcare professionals and the donation system, and damage the doctor–patient relationship.

Support for other types of organ donation systems

3.12 In some instances respondents indicated support for other types of system: e.g. variations on: (i) a 'hard' opt out system based on presumed consent with no account taken of the wishes of family members, (ii) a hard opt in system in which family members cannot overrule an individual's stated wishes, (iii) a 'mandatory choice' system in which people are required to either opt in or out, (iv) systems incorporating reciprocity (i.e. where eligibility to receive an organ is linked to willingness to donate) or allowing donors to state preferences regarding recipients.

3.13 In particular, it should be noted that some of the individuals who indicated that they did not support the principle of a soft opt out system in completing the tick box at Question 1 went on to note their preference for a hard opt out system, or their preference for a soft over a hard opt out option if an opt out model was to be adopted; conversely some of those

⁵ A few respondents said they were currently on the ODR but would opt **out** if an opt out system was introduced.

expressing support for the principle of a soft opt out, also indicated that they would also support a hard opt out system.

Other issues raised by respondents in relation to an opt out system

3.14 Two more substantive issues were raised by respondents. These were: (i) the issue of human rights and compliance with human rights legislation, and (ii) the concepts of informed consent versus authorisation. These were discussed as follows:

- **Informed consent versus authorisation:** Respondents – particularly those opposed to a soft opt out system – were concerned that the ‘deemed authorisation’ proposed by the Scottish Government represented a move away from the concept of ‘informed consent’, i.e. explicit consent based on full understanding of relevant information. They thought that organ donation should always require explicit, conscious authorisation. Indeed, there was a view that joining the ODR within the current opt in system did not fully meet the standard of ‘informed consent’. Other respondents stressed the importance of maintaining the concept of ‘consent’ as requiring an active decision, given its role in other aspects of life (medical and other). Related to this, some highlighted the importance of clarity regarding terminology on this issue, and ensuring this was appropriately reflected in relevant documentation and guidance.
- **Human rights:** Some respondents expressed general concerns that a system based on ‘deemed authorisation’ may contravene an individual’s human rights. Others suggested that, whatever system was in place, it was important that the law in this area be compliant with human rights legislation, and in particular, that there was a clear legal basis for reconciling the rights of individuals and their families in the process for authorising donations. The importance of protecting the rights of children in particular and adhering to the United Nations Convention on the Rights of the Child in any system was noted by one organisation which recommended carrying out a Children’s Rights and Wellbeing Impact Assessment.

3.15 Respondents also made a number of other more general comments, regardless of whether they supported or did not support the principle of soft opt out system:

- Current evidence is mixed or inconclusive and more evidence is therefore needed on: (i) what works (including in relation to the impact of the recently introduced soft opt out system in Wales), and (ii) public attitudes and behaviours.
- There needs to be more public debate on the implications, benefits and risks of the various options.
- Whatever system was in place there was a need to raise awareness of organ donation, encourage family conversations, and improve health service infrastructure, staff training and family support.

4. The current opt in system (Q2)

4.1 As well as considering the possibility of introducing a soft opt out system, the consultation paper noted that keeping the current opt in system remained an option. In that context, Question 2 asked respondents about changes which might be made to the current opt in system to increase the number of organs available for transplant:

Question 2: Are there any changes you would make to the current opt in authorisation system, other than moving to an opt out system?

4.2 Altogether 455 respondents (420 individuals and 35 organisations) replied to Question 2. In 100 cases (just over a fifth of those who replied), the respondent simply answered 'no' or 'none'. In the remaining 355 responses, comments focused on the following main themes: taking account of the views of family members; initiatives within the health service to increase donations; encouraging individuals to sign-up to the ODR; promotion and advertising of organ donation; and incentives for becoming an organ donor. The first of these themes – that of taking account of the views of family members – is discussed in the following chapter (Chapter 5) along with related comments made in response to Question 3 which focused on situations where an individual has stated their wishes to be an organ donor, but the donation is opposed by family members. The other themes are discussed below, as follows:

- **Pursuing initiatives within the health service to increase donations:** Respondents suggested a wide range of actions which might be pursued within the health service to increase successful donations. These included providing additional specialist staff and / or appropriate training, information and support for all staff; ensuring appropriate practices and protocols were in place in healthcare settings to allow organs to be considered for donation; ensuring best practice in advising and supporting families in potential donation situations; developing and investing in Intensive Care Unit facilities and technology to support the viability of organ donation; making the donation pathway more efficient; and exploring options for widening the criteria for acceptable organs.
- **Taking active steps to encourage sign-up to the ODR by individuals:** Respondents often thought a more proactive approach to encouraging sign up to the ODR should be pursued. They suggested: (i) providing opportunities to sign up to the ODR in a range of contexts – e.g. via GPs, at blood donation sessions, at health screening appointments, at pharmacies, or as part of interactions with other public or private agencies; and (ii) taking a more direct approach to inviting people to sign up by, for example, contacting all young people directly as they turn 16.
- **Increasing promotion and advertising of organ donation:** Respondents frequently highlighted the importance of increased and ongoing advertising and promotion through a wide range of channels – generally, and in relation to particular sub-groups (e.g. young people, religious and ethnic minority communities) – as a way of encouraging discussion within families and across society more widely, bringing about a change in attitudes, and increasing ODR sign-up. The introduction of education on organ donation in schools was endorsed. It was suggested that communication campaigns might make use of social media and routine healthcare correspondence, and might emphasise good news stories, or remind people that they might need a transplant one day.

- **Improving information on organ donation and transplantation:** Some respondents thought that improved information was required so that people were able to make a properly informed decision about whether they wished to be an organ donor. It was suggested that information should be provided in user-friendly non-technical language, and should explain the various options open to people in becoming a donor including the option to opt **out**, what happens during the donation and transplantation process, and how and where to join the ODR.
- **Administrative improvements:** Respondents thought it should be easier for people to join the ODR, and to check and update their registration status (e.g. online, via app, or by other offline means). They also suggested that a person's ODR status should be readily accessible to healthcare staff with information held on a central database or routinely recorded in an individual's medical records.
- **Providing incentives to becoming a donor:** In a small number of cases, individual respondents suggested that 'incentives' might be introduced to encourage more people to sign up to become organ donors. These suggestions included making sign-up to the ODR a condition for receiving an organ; allowing people to prioritise their own family as organ recipients, or to indicate preferences as to who might benefit from their organs; or providing funeral funding for organ donors.

4.3 However, it is worth noting that most of the recommended actions above, excluding the points covered in the final bullet point, are either already in place in some form or are continuing to be developed in Scotland. Some respondents – organisations or individuals with a professional link to the health service in particular – recognised this in their comments, but in some cases called for such initiatives to be further developed. Such respondents often also highlighted the importance of a 'package' of measures being introduced. There was, in particular, a frequently expressed view that a range of factors influenced donation rates and these have to be addressed in a coherent and integrated way in order to increase organ donations. Respondents often cited the 'Spanish Model' which was seen to offer a fully integrated and resourced approach to improving donation rates (albeit one that was combined with a form of opt out authorisation system).

4.4 Some respondents made suggestions while also stating a preference for an opt out system; others made it clear that they favoured retaining the current opt in system, albeit with changes to improve its effectiveness, or they thought that efforts should be made to maximise the effectiveness of the current system before an opt out system was considered.

4.5 Not all respondents who commented at Question 2, however, offered suggestions on how the current opt in system might be changed. Some expressed the view that no change was needed – these respondents, including some organisations and individuals who worked in the healthcare field – thought the current system worked well, and that recent and current initiatives (reference was made to the UK strategy 'Taking Organ Transplantation to 2020' and a 'Donation and Transplantation Plan for Scotland 2013–2020') were already having a positive impact on increasing the number of successful organ donations. Others thought that making changes to the current opt in system would not be effective in achieving an increase in the number of organs donated for transplant, and they argued for a move to an opt out system instead.

5. Taking account of the views of family members (Q3)

5.1 This chapter presents respondents' comments on taking account of the views of family members.

5.2 In the current opt in system, the donation is discussed with family members before a donation proceeds, even in cases where someone has stated a wish to be an organ donor. Although there is no statutory requirement to give precedence to the views of family members in this situation, a donation would not proceed if family members were opposed to it. The consultation explained that the support of the family is key to providing background information on the potential donor to enable the transplant surgeons to decide whether organs or tissue are likely to be safe for transplantation. Question 3 (a tick-box question with no space provided for additional comments in the online questionnaire) asked for views on whether a donation should or should not proceed in a situation where families oppose a donation even though the individual has indicated their wishes to be an organ donor:

Question 3: Where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor's family opposes the donation?

5.3 The chapter presents the response to Question 3 before going on to provide an analysis of relevant comments. Although there was no follow-up question asking for additional comment, respondents often did explain their answer to Question 3 (many doing so at Question 15) – organisations were particularly likely to do so. In addition, taking account of family views was a commonly raised issue at Question 2 (104 respondents discussed this issue at Question 2 – see Chapter 4). The analysis of views presented below therefore draws on comments made across a range of questions with regard to the role of families in authorising organ donation following the death of an individual.

5.4 A total of 800 respondents answered Question 3 – 772 individuals and 28 organisations. Table 5.1 shows that there was a clear difference in views between organisational and individual respondents. The majority of individual respondents (around four-fifths) were in favour of proceeding with the donation. In contrast, most organisations (around two-thirds) thought that the donation should not proceed. Among organisations, there were, though, some differences: most NHS / local authority and professional groups thought the donation should not proceed, whereas charities, voluntary sector or patients' rights groups and faith groups were split in their views.

Table 5.1 – Question 3: Where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor's family opposes the donation?

Respondent type	Medical staff should still proceed with the donation	Medical staff should not proceed with the donation	Total
NHS and / or local authority	3	7	10
Charity, voluntary sector or patients' rights groups	4	4	8
Professional groups and regulatory bodies	–	4	4
Faith groups	3	3	6
Organisation total	10	18	28
Organisation percentage	36%	64%	100%
Individual respondents	640	132	772
Individual percentage	83%	17%	100%
Total (organisations and individuals)	650	150	800
Total percentage	81%	19%	100%

Arguments in favour of adhering to the individual's wishes

5.5 The role of the family in authorising organ donation in the current opt in system was a key issue discussed at Question 2 which asked for views on how the current opt in system might be changed if an opt out system were not introduced. Respondents often simply said that the views of the individual should always take priority, that a family should not be able to 'veto' the stated wishes of an individual, or that wishes expressed via the ODR or in other ways should be regarded as being legally binding. Some specifically suggested that there should be no requirement to consult with or seek authorisation from family members in the organ donation process. Individuals were particularly likely to offer this view. It was common among this group for respondents to say that, should an opt out system not be introduced, they would like to see the current opt in system changed so that family members could not overrule the wishes of individuals.

5.6 Organisational respondents who indicated support for adhering to the individual's wishes were less likely to express their views in black and white terms, but rather emphasised that the wishes of the potential donor should be given precedence, even if the family objected, if that individual's views were clear and / or they had made their views known in writing.

5.7 A few respondents provided fuller explanations of their views, and thought that there were moral, ethical or legal reasons for respecting the views of the potential donor, particularly where they could be said to have given 'informed consent'. It was pointed out that to do otherwise gave families rights over the individual which they would not have had if the person were still alive, or did not have in other matters (e.g. in relation to a person's will). Others pointed out that individuals and their families did not always share the same views or beliefs, and that allowing families to overrule the wishes of an individual might mean that, in death, an individual was subject to views or beliefs which they, themselves, may not have agreed with. Others commented that individuals may be estranged from their family, and it would not therefore be right for the families' views to take precedence.

5.8 Some recognised that this was inevitably a very difficult time for families, but did not think that that gave families the right to overturn a decision made by the potential donor. Indeed some thought that bereaved families were not well placed to make a decision on this issue because of the highly emotional situation they were in. It was also argued that families often took comfort following the death of a loved one from the fact that others had benefitted from an individual's organs, and sometimes regretted not agreeing to a donation proceeding.

5.9 The following points were also made, all on a less frequent basis:

- Some respondents argued that there was no legal basis for allowing families to overrule the views of individuals in the current opt in system. (There was also a related call for clarity on this issue.)
- Some thought that respecting the wishes of individuals was important for the integrity of the donor system.
- It was suggested that public opinion favoured precedence being given to the wishes of the individual.

Arguments in favour of allowing families to override the wishes of individuals

5.10 As shown in Table 5.1, organisational respondents were more likely than individuals to think that a donation should not proceed if it is opposed by the donor's family. Organisations were also more likely than individuals to explain the reasons for this view. Across both groups however, respondents thought that proceeding with a donation against the wishes of a family would:

- Exacerbate the distress of families involved in such situations, and compromise the duty of care which healthcare professionals had to families as well as patients
- Risk alienating families, and damaging public confidence in the medical profession and public support for organ donation and the organ transplantation programme
- Risk patient safety as family cooperation was important in establishing medical history and suitability to proceed with a donation.

5.11 More generally, some thought that families had a right to express their views, and that it was appropriate for families to be involved in decisions about organ donation. Indeed, it was argued that to do otherwise would be out of step with expectations within society. It was also suggested that proceeding with a donation in these situations would have little impact on overall donations, and that there were other, more effective ways of achieving the objective of increased donations.

5.12 Some thought that the stated views of the individual should generally take priority, but they highlighted specific circumstances where they thought that the views of families should be given precedence. This included situations where proceeding with a donation would cause extreme distress to the family (e.g. because of religious beliefs), or where the family believed that the person had changed their mind about wanting to be an organ donor – it was noted that family members were the people most likely to know this – although there was a view

that proof of a change of heart should be required to overturn the stated wishes of an individual.

5.13 Some respondents – organisations in particular – did not think that donations should proceed against the wishes of families, but did think that every effort should be made to encourage families to respect the wishes of individuals, and to support families as they made their decision on this difficult issue. It was suggested that discussions should focus on whether families had any reason to believe that the individual's stated views were no longer valid, rather than being presented as an opportunity for families to make their views known. It was further suggested that families should be explicitly informed of the wishes of the potential donor; should be encouraged to respect stated wishes; should be informed of the legal framework which does not require family authorisation; should be made aware of the positive effect of transplantation; and should be required to formally sign their decision to overrule the wishes of the deceased as a way of highlighting the significance of such a decision. (It was noted by some that such practices were, in fact, already being followed.)

Other comments

5.14 A range of further points were made by respondents in discussing the issue of taking account of the views of families. These included the following:

- Situations in which families oppose donation were complex and there was a need to balance the importance of respecting the views of the individual with the need to consider the wellbeing of the family and the likelihood of significant distress.
- Professional judgement played a part in decisions regarding organ donation, and there was existing guidance for healthcare staff which was relevant to dealing with this situation.
- It was important that specialist organ donation staff and appropriately senior staff were involved in discussions with families.
- Different factors were at play in situations where the donor's wishes were not clear – indeed, it was noted that a significant proportion of donations currently proceed on the basis of family authorisation in the absence of clear information on the views of the potential donor. A few respondents suggested that, in this way, the proposed opt out system was in fact little different to the current system. While some endorsed this situation, others felt that this was not acceptable in that it risked violating the rights of individual to have their (unknown) wishes respected. Such respondents advocated the importance of explicit authorisation by individuals.

5.15 Others discussed the wider organ donation system and made the following points:

- Publicity campaigns should emphasise the importance of individuals discussing their wishes with their family as a way of ensuring that these are not overruled.
- The process of joining the ODR might be changed in some way to avoid the situation of families overruling the wishes of individuals. Suggestions included following:
 - Making explicit opt in to the ODR legally binding – it was argued that this would reduce stress on bereaved families by avoiding the situation whereby they are asked to authorise a donation.

- Amending the process for signing up to the ODR so that it incorporates an indication of family awareness / family authorisation, or a requirement for witnesses (one of whom could be a family member).
 - Including a notification in the ODR sign up process to ensure people are aware that their family will be asked to authorise a donation in the event of their death.
 - Regular updating of ODR entries.
- Research should be undertaken to investigate the reasons families overrule the wishes of individuals and to explore ways of reducing the likelihood of this happening, as well as to find out more about the longer term feelings of families involved in organ donation discussions with various outcomes.

6. The operation of a soft opt out system (Q4 and Q5)

6.1 This chapter discusses respondents' views on the proposed operation of a soft opt out system, and covers the responses to consultation questions 4 and 5.

6.2 The consultation paper explained that a workable soft opt out system would involve: (i) high profile awareness-raising campaigns for at least 12 months before the introduction of the new system, and on a regular basis after implementation; and (ii) upon the death of an individual in hospital, a process of undertaking a range of checks to decide whether a donation from that individual could proceed.

6.3 The consultation paper explained that five checks would be undertaken as follows:

- If the person had registered as opting out, the donation would not proceed (unless the family provided evidence that the person had confirmed in writing that they had changed their mind)
- If the person had registered as opting in, the family would be informed and the process to examine the feasibility of a donation would begin (unless the family provided evidence that the person had confirmed verbally or in writing that they had changed their mind)
- If the person was not on the ODR, the family would be approached to discuss this. In the absence of any other information, the person would be deemed to have authorised donation. The person's family / friends would be asked if the person had expressed any objections to organ donation. If the person was not known to have expressed any objections, then the assumption would be that the donation could proceed – this is known as 'deemed authorisation'.
- However, potentially, there is still scope for a donation not to proceed if it was clear that going ahead with a donation would cause distress to the family and result in their refusal to provide important background information.
- In the relatively rare cases where a person did not have any family or close friends (or none that could be contacted within the necessary timeframe) – and if the person was not in a category where explicit authorisation was required (i.e. one of the 'excepted categories') – then donation could be considered to be authorised unless the person had opted out. However, in such cases, NHS staff would need to consider whether they had sufficient information about the medical history of the patient to ensure that the patient's organs / tissues would be safe to transplant.

6.4 The consultation asked the following questions in relation to these checks.

Question 4: If there was a soft opt out system, what do you think of the proposed checks above?
[These are sufficient to decide if a donation can be deemed to be authorised / These are not sufficient to decide if a donation can be deemed to be authorised / Don't know]

Question 4a: If you think these are not sufficient, what other checks would be needed (apart from those covered in Questions 6 to 8 below)?

Question 5: In any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family? [The donation should still proceed / The donation should not proceed / Don't know]

Views on the proposed checks (Q4 and Q4a)

6.5 Respondents were asked what they thought of the proposed checks set out in the consultation paper. (See paragraph 6.3 above.)

6.6 Altogether, 798 respondents replied to this question – 33 organisations and 765 individuals. Two-thirds (67%) of organisational respondents and 86% of individual respondents agreed that, in a soft opt out system, the proposed checks set out in the consultation paper were sufficient to decide whether the donation should proceed. However, 4 out of 6 faith groups thought that the checks outlined were not sufficient (Table 6.1).

Table 6.1: Q4 – If there was a soft opt out system, what do you think of the proposed checks set out in step 2?

Respondent types	These are sufficient to decide if a donation can be deemed to be authorised	These are not sufficient to decide if a donation can be deemed to be authorised	Don't know	Total
NHS and / or local authority	9	1	1	11
Charity, voluntary sector or patients' rights groups	8	–	1	9
Professional groups and regulatory bodies	4	3	–	7
Faith groups	1	4	1	6
Organisation total	22	8	3	33
Organisation percentage	67%	24%	9%	100%
Individual respondents	657	68	40	765
Individual percentage	86%	9%	5%	100%
Total (orgs and individuals)	679	76	43	798
Total percentage	85%	10%	5%	100%

6.7 Respondents who indicated that the checks were not sufficient, or who said they did not know whether the checks were sufficient were then asked what other checks they thought would be needed (Question 4a). Ninety-eight (98) respondents commented in response to this question – 18 organisations and 80 individuals.

6.8 Of those who commented, 67 considered that the proposed checks were insufficient, and seven said they didn't know if the checks were sufficient. In addition, four organisations provided comments, but did not tick any of the boxes at Question 4.

6.9 The remaining 20 respondents who commented had indicated that they were satisfied with the checks proposed. The comments of this latter group generally described the proposed checks as 'adequate' (or 'more than adequate'), 'sensible', 'reasonable',

‘comprehensive’, and ‘robust’. In exceptional cases, the checks were described as ‘excessive’ by respondents who called for all organs to be available for transplant unless there was clear evidence that an individual had opted out. Where further comments were made by these 20 respondents, they focused on the following issues:

- **Family authorisation:** Some respondents argued that family members should not be able to overrule a choice by an individual to opt in, and it was noted that the Human Transplantation (Wales) Act 2013 does not give family members the power to override the deemed authorisation of an adult with capacity. However, there was also the contrasting view that, for ethical reasons, family authorisation would remain essential. Some respondents also expressed concern about the potential impact on families in a deemed authorisation situation (i.e. where an individual had **not** opted in to the ODR) if a donation proceeded without family authorisation.
- **Exceptions to deemed authorisation:** Some respondents expressed satisfaction with the proposed checks, but suggested that exceptions should be made in certain cases, for example, in relation to children, or where a potential donor lacked the capacity to decide about organ donation. (These issues were addressed as part of the consultation – see Chapter 7.)
- **Type of donation:** Some respondents suggested that these checks were sufficient for most types of donations, but not for less common donations or donations which could result in the disfigurement of the donor (the examples given were facial donation, and tissue such as skin and bone). (This issue was addressed as part of the consultation – see Chapter 8.)
- **Improving IT access to a donor’s medical history:** Some respondents suggested that efforts could be made to improve access to a potential donor’s medical history, thus helping to reduce the burden on family members to provide this when they are grieving.
- **Development of a Code of Practice:** In relation to the Welsh context, it was noted that a Code of Practice had been drafted by the Human Tissue Authority and approved by the Welsh Government. This provides practical advice and guidance as to the role of family and friends and what should be done when the family are unhappy about donation. It was suggested that a similar Code of Practice should be developed in Scotland.

Views of those who indicated that the checks were NOT sufficient

6.10 Respondents who thought the proposed checks set out in the consultation document were **not** sufficient largely expressed opposition in principle to the introduction of a soft opt out system. The main arguments from this group were that:

- It should never be assumed that an individual had authorised organ donation unless that individual had done so explicitly.
- It would be a violation of human rights for the state to assume ‘ownership’ of an individual’s body when they are dying.
- The views of the person’s family (or nearest relative) must always be respected and the family must agree with the process in order for a donation to proceed.

- It is not realistic to assume that a person's family would know what their wishes are in relation to organ donation.
- There is a significant potential for IT failure or human error, where opt out instructions had been lost or mistakenly overlooked.

6.11 Less often, this group made suggestions about additional checks that could be included in a soft opt out system. Many of these focused on the situation in which an individual's family / friends were unable to be contacted or identified. There were three different perspectives on what should happen in such a situation:

- Inability to contact family or close friends within the required timeframe should result in the donation not proceeding.
- A third party (suggestions included a sheriff, advocate, or Procurator Fiscal) should be asked for a 'rapid review' of the case to ensure that it was appropriate to proceed, that all reasonable attempts to identify family had been exhausted, and that all procedures had been complied with.
- A solicitor should be appointed to act in the best interests of the deceased.

6.12 Some in this group also echoed the point made in the consultation paper that if a person had no family / friends who could be contacted, there may be insufficient background information about the patient to allow the donation to proceed in any case.

6.13 This group also made the following suggestions: (i) training GPs to have discussions with their patients about organ donation and how to incorporate decisions about this into a 'living will' (either to opt out or opt in); and (ii) introducing a mechanism for those who had explicitly opted out or opted in to check and update their registration on an annual basis.

6.14 Within this group of respondents, there were also a few individuals who held an opposing view. That is, in relation to the suggestion that a donation may not proceed if it might cause distress to the family, these respondents argued that the family should not have the right to refuse.

6.15 A small number of other specific issues were raised by those who thought the proposed checks were not sufficient. These focused on: (i) the proposed awareness raising campaigns and (ii) the requirement for written versus verbal evidence of a potential donor's change of mind. Both of these are discussed briefly here.

The proposed awareness raising campaigns

6.16 A range of respondents highlighted the importance of ongoing awareness raising if a soft opt out system is introduced. It was noted that the campaign to raise awareness of the Human Transplantation (Wales) Act 2013 had a lead in time of two years. Such a campaign would require considerable resources. It was also noted that, even after the Welsh campaign, surveys showed that over one-third of people in Wales were still unaware of the need to opt out of donation if they do not want their organs to be donated. Respondents made the following additional points:

- Any communications campaign conducted prior to the implementation of the system would have to be repeated on a regular basis in the future. Some respondents queried whether it would be possible for such a campaign to be sustained long-term.
- Communication would also need to be targeted appropriately to specific sub-groups of the general population, including children, ethnic minorities (people whose first language is not English), those lacking capacity, hard-to-reach groups (such as homeless people), and visitors to Scotland.
- It is important for any awareness campaign to include clear information about how to opt out. A lack of information could disadvantage people who might have wished to opt out, but did not know how to do so. It was thought this could potentially result in legal challenges.
- The effectiveness of any communications campaign should be evaluated regularly.

The requirement for evidence of a potential donor's change of mind

6.17 There were several points made in relation to this requirement. Organisational respondents from the NHS commented that providing evidence of a change of mind 'in writing' would be impractical in most cases, onerous and uncompassionate. One respondent discussed the Human Tissue Authority guidelines for Wales on verbal and written authorisation in the context of a deemed authorisation system, stating that there was no requirement for 'written evidence' in the Welsh system.

6.18 Some individual respondents (all of whom were opposed to the principle of an opt out system) echoed the first point, stating that where a person is gravely ill, it would not be reasonable or appropriate to ask their relatives to leave their bedside to search for their written instructions.

6.19 Other respondents queried why written confirmation was required as evidence of a person's change of mind where they had registered as opting out, but verbal confirmation was sufficient as evidence of a person's change of mind where they had registered as opting in. It was argued that, if written evidence is required at all in an opt out system, then it should be required to overrule a donor's expressed decision to opt in. This is because if a person had registered their wishes to be a donor, then that person would have taken active steps (beyond that which is required) to make their wishes known.

6.20 Finally, there was also a group of respondents who expressed concern about whether 'verbal evidence' of a change of mind given by families could be relied upon. This group argued that such verbal evidence should not play a factor in decisions taken by medical staff. This latter view was expressed by respondents who were supportive of the principle of an opt out system.

Decision-making where a donation may distress the donor's family (Q5)

6.21 Consultation Question 5 was a closed question asking respondents for their views about what should happen if a deemed authorisation donation was likely to distress the potential donor's family. The consultation paper suggested that, in such cases, a decision could be taken for the donation not to proceed.

6.22 Altogether, 805 respondents replied to this question – 32 organisations and 773 individuals. Most organisational respondents (23 out of 32, 72%) believed that if deemed authorisation donation was likely to distress the potential donor’s family, then the donation should not proceed – although, there were divided views on this question among charities and voluntary sector groups. A small majority of individual respondents (57%) were in favour of the donation proceeding in this situation (Table 6.2).

Table 6.2: Q5 – In any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor’s family?

Respondent type	The donation should still proceed	The donation should not proceed	Don't know	Total
NHS and / or local authority	1	10	1	12
Charity, voluntary sector or patients’ rights groups	4	4	1	9
Professional groups and regulatory bodies	–	3	1	4
Faith groups	1	6	–	7
Organisation total	6	23	3	32
Organisation percentage	19%	72%	9%	100%
Individual respondents	439	242	92	773
Individual percentage	57%	31%	12%	100%
Total (organisations and individuals)	445	265	95	805
Total percentage	55%	33%	12%	100%

6.23 Chapter 5 discussed respondents’ views about what should happen in a situation where a person had opted in to the ODR or otherwise explicitly authorised organ donation, but the family opposed the donation. If the findings shown in Table 6.2 above are compared with those set out in Chapter 5 (Table 5.1), it can be seen that a smaller proportion of individuals were in favour of a donation proceeding in a deemed authorisation situation as compared to a situation where the donor had explicitly stated their wishes (57% in a deemed authorisation situation vs 85% in an explicit authorisation situation). Similarly, a larger proportion of the organisational respondents were also of the view that a donation should not proceed in a deemed authorisation situation if the donation is likely to distress the potential donor’s family.

6.24 Although Question 5 did not include space for comments, some respondents – most often organisations – did explain their views, either along with their tick-box response for those responding offline, or at Question 15 for those completing the online questionnaire. While some respondents were strongly against families being able to overrule decisions (deemed or otherwise), others prioritised the wishes of the family, and cited the risk of causing distress and increasing pressure on relatives as key reasons for not supporting an opt out system (see Chapter 3).

6.25 However, amongst those respondents who commented specifically on the situation described at Question 5, most of which were organisations, the most common view was that it would be appropriate for specialist staff to discuss the issue with the family to try to alleviate their concerns, and encourage them to support the decision of the potential donor (who

chose not to opt out). Respondents stressed that this should be done sensitively, but agreed that the donation should not proceed if it was going to cause significant distress. Some respondents highlighted the importance of professional judgement based on the circumstances of any individual case. It was also noted that professional guidance was available to healthcare staff in dealing with situations such as this, and it was further suggested that if an opt out system were introduced, that this scenario should be addressed in a Code of Practice.

6.26 Some respondents did, however, suggest that establishing the cause of any distress was crucial to the ultimate decision on proceeding as families should only be able to intervene if they believed the individual would not have wished the donation to proceed, not just because they, themselves, did not wish it to proceed.

6.27 A few respondents also raised ethical considerations, querying: (i) the right of families to make decisions in the absence of any indication of the individual's own views, and (ii) the extent to which families may feel pressurised to agree to the donation if this was perceived as the 'default' position.

6.28 A small number of additional points were made as follows:

- That over time, as people became accustomed to the opt out system and organ donation became the norm, the likelihood of family distress and objections would reduce
- That the likelihood of families agreeing to donation was greater if the individual's views were known and that further work to encourage conversations within families about organ donation would help avoid this situation
- That the continued involvement of families in the authorisation process was an important positive feature of the sort of soft opt out system proposed in the consultation paper
- That further research into understanding family distress in such situations and the long term impact of overriding family objections would be useful.

7. Explicit authorisation in a soft opt out system (Q6 – Q9)

7.1 This chapter discusses respondents' views in relation to consultation questions 6 to 9. These questions sought views about the 'excepted' categories of people for whom explicit authorisation – either from the person themselves or from their family – would still be required in a soft opt out system.

7.2 The consultation paper explained that in a soft opt out system, deemed authorisation for donation would generally apply. However, some exceptions to the general rule would also exist. The consultation paper set out proposed exceptions that would apply in relation to three specific groups, referred to as 'excepted' categories of people:

- Someone who, over a period of time before their death, did not have capacity to take a decision on donation
- A child under a certain age (the consultation paper suggested that deemed authorisation might only apply for children older than 16, but sought views on this issue)
- Anyone who had not been resident in Scotland for at least 12 months before their death.

7.3 If an individual was in one of these three categories at the time of their death, deemed authorisation would **not** apply; rather, the proposal was that donation could only proceed if explicit authorisation was given.

7.4 The consultation sought people's general views about the appropriateness of the three proposed excepted categories. It also sought specific views on (a) the circumstances in which an adult should be viewed as 'not having capacity' to make their own decisions about donation; and (b) for children, the age under which donation would only be able to take place with explicit authorisation – and above which deemed authorisation would apply. Finally, views were invited about whether local authorities should (or should not) be allowed to authorise donation of organs and tissue from a child in care if no parent is available. The consultation asked four questions about these matters.

Question 6: If there was a soft opt out system, what do you think about the categories of people (described in the consultation paper, pages 15 to 17) for whom explicit authorisation would still be needed from the person themselves or a family member? [The categories are sufficient / The categories are not sufficient / Don't know]

Question 6a: If these are not sufficient why do you think this?

Question 7: In what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?

Question 8: Under what age do you think children should only be donors with explicit authorisation? [Under 12 / Under 16 / Under 18 / Other, please specify]

(continued)

Question 9: For children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available? [They should be allowed to authorise donation of a child’s organs or tissue in those circumstances / They should not be allowed to authorise donation of a child’s organs or tissue / Don’t know]

Excepted categories of people (Q6 and Q6a)

7.5 Question 6 asked respondents about the three categories of people for whom explicit authorisation should still be needed in a soft opt out system. Respondents were asked to indicate whether or not these categories were sufficient. If the respondent indicated that the categories were not sufficient, a follow-up question (6a) invited further comment.

7.6 Altogether, 797 respondents (33 organisations and 759 individuals) replied to the initial closed part of this question. Around three-quarters of both organisational and individual respondents expressed agreement with the three proposed categories of people for whom explicit authorisation would be required in a soft opt out system; that is, they believed these categories were sufficient. Only faith groups among the organisational respondents were more likely to say that the categories were **not** sufficient (Table 7.1).

Table 7.1: Q6 — If there was a soft opt out system, what do you think about the categories of people for whom explicit authorisation would still be needed from the person themselves or from a family member?

Respondent type	The categories above are sufficient	The categories above are not sufficient	Don't know	Total
NHS and / or local authority	10	2	–	12
Professional groups and regulatory bodies	7	–	–	7
Charity, voluntary sector or patients' rights groups	6	2	–	8
Faith groups	1	4	1	6
Organisation total	24	8	1	33
Organisation percentage	73%	24%	3%	100%
Individual respondents	602	93	64	759
Individual percentage	79%	12%	8%	100%
Total (organisations and individuals)*	626	101	65	792
Total percentage	79%	13%	8%	100%

7.7 One hundred and twenty-five respondents (19 organisations and 106 individuals) made comments in response to Question 6a explaining more about their reasons for not thinking the categories proposed were sufficient. This includes 14 respondents who did not tick any of the boxes given at Question 6, and 14 others who had indicated they thought the proposed excepted categories were sufficient. The comments of the latter group are

discussed briefly before going on to consider all other comments made in response to this question.

Views of respondents who thought the categories were sufficient

7.8 Although question 6a asked for further information from those who thought the proposed excepted categories were not sufficient, 14 respondents who agreed with the categories nevertheless offered additional comments.

7.9 In some cases, these comments simply stated satisfaction with the categories, saying that they were 'reasonable' or 'appropriate', without offering further information. However, others either disagreed with one or more specific aspects of the proposals, or they suggested additional categories – while nonetheless expressing general support for what was proposed. Any specific comments made within this group overall were made by just one person.

7.10 In relation to each of the three proposed categories, this group suggested:

- Regarding a person with a long-term incapacity: if such a person had made an earlier decision to opt in, this earlier decision should continue to be respected even if the person had a long-term incapacity at the time of death. There was also a view that adults with incapacity should only be treated as exceptions to deemed authorisation if this had taken place before the opt out system came into operation.
- Regarding children under a certain age: there were views that age 12 was too young for children to be able to self-authorise; there was also a view that any wish by a child to donate their organs after death should involve a discussion with the child's parents.
- Regarding those who were resident in Scotland for less than 12 months: there was a view that the period of restriction should be shorter than 12 months.

7.11 A small number of addition points were raised by this group: (i) there was a query about whether individuals holding certain religious beliefs should be included in the list of excepted categories; and (ii) it was noted that the proposal not to apply deemed authorisation in relation to these categories was consistent with current practice. Regarding the latter point, the individual who raised it therefore questioned the need to change the current system given the time and training that would be required to implement a new system, and the potential for this to take away focus and resource from current practice.

Respondents' reasons for disagreeing with the excepted categories

7.12 Among those who indicated that the proposed excepted categories were not sufficient, the main reason given was that the respondent was opposed in principle to a soft opt out system. These respondents believed that in all cases, explicit authorisation should be required for organ or tissue donation. Some within this group also believed that the proposals set out in the consultation paper had the potential to cause distress to grieving families after the death of a loved one if explicit authorisation were routinely sought for people in the excepted categories.

7.13 Other comments focused on one or more of the three proposed excepted categories, and in each case a range of (often conflicting) views were expressed. Some respondents

clearly supported an opt out system and felt the proposals were too restrictive, while others were opposed to an opt out system and felt the proposals were unethical.

Category 1 – People lacking capacity

7.14 Regarding the proposal to require explicit authorisation for someone who, over a period of time before their death, did not have capacity to take a decision on donation, the following views were expressed:

- Some respondents commented specifically on the issue of ‘the period of time before death’. In most cases, these respondents thought that if the law on organ and tissue donation changed and an individual chose not to opt out during a period of years after the law changed, then, even if they later lost the capacity to make decisions, deemed authorisation should continue to apply. Thus, only people who had lost the capacity to make decisions before the system came into operation should require explicit authorisation.
- Related to this, any previous decision to opt in (explicit authorisation recorded earlier) should continue to be honoured even if an individual loses the capacity to make decisions later in life.

7.15 In contrast to these views, other respondents thought that people without the capacity to consent prior to their death should not be considered for organ or tissue donation under any circumstances.

Category 2 – Children under a certain age

7.16 Respondents’ comments in relation to the second proposed excepted category did not always relate directly to the question asked. These comments tended to focus on two issues:

- The age at which a child can self-authorise: Most of those commenting on this particular issue referred to the comment in the consultation paper that children of 12 years old or over are able to self-authorise their own donation. In general, respondents who commented on this thought that age 12 was too young for a child to make their own decision to donate their organs or tissue. They thought that parental authorisation should be required for children up to age 16 or 18, regardless of the child’s wish to opt in. The contrasting view, expressed less commonly, was that parental authorisation should not be required at all for a child over age 12 if the child had opted in to the ODR or otherwise explicitly expressed a wish to donate their organs or tissue.
- The age at which deemed authorisation would apply: While some respondents agreed with the consultation paper that deemed authorisation should apply from age 16 and above, others thought it should be increased (to 18 or 21). One organisational respondent commented that the Welsh legislation defines a ‘child’ as a person under 18, and does not permit deemed authorisation until age 18. Some respondents went further, arguing that explicit parental authorisation should always be required for children (including up to age 18 or 21) regardless of any explicit authorisation from the child. Less commonly, it was suggested that children under 18 should be entirely exempted from organ or tissue donation unless they had consistently expressed – over a period of years – the desire to be a donor.

7.17 There was also a view, expressed much less often, that children of all ages should be included in the soft opt out system and deemed authorisation should apply in all cases unless their parents had previously opted out on their behalf.

7.18 Respondents also highlighted disparities between these proposals and other legislation (for example, the age at which children can vote, drive, drink alcohol, etc.).

Category 3 – People resident in Scotland for less than 12 months

7.19 The proposal to require explicit authorisation for people resident in Scotland for less than 12 months attracted the largest volume of comments. This may be partly because there was no follow-up question in the consultation about this group, whereas additional questions were included in relation to adults with incapacity (Question 7), and donation by children (Question 8). (See below.)

7.20 Once again, a wide range of views were expressed. These generally focused on: (i) the potential difficulties of obtaining explicit authorisation from the family members of people who may be relatively recent arrivals in Scotland; (ii) the residence status of students in Scotland; (iii) cultural / religious differences in other countries coupled with communication challenges where a person speaks another language; and (iv) the period of time for which explicit authorisation would be required among people who have recently become resident in Scotland. Each of these themes is covered briefly below.

- **Potential difficulties of obtaining explicit authorisation from family members living overseas:** Respondents highlighted the practical difficulties of obtaining authorisation for organ donation from family members who may live overseas, particularly where telecommunications infrastructure is poor, or where English is not spoken as a first language.
- **Status of students in Scotland:** Some respondents commented that the example given in the consultation paper regarding students was potentially confusing. These respondents noted that students studying in Scotland from outside the country may not see themselves as resident in Scotland and so not appreciate the requirement to opt out. They also highlighted the potential for distressing misunderstandings with the families of these students. Other respondents believed that the consultation paper was contradictory in relation to students who may not be permanently resident in Scotland over a 12-month period. The general view was that, unless a student had opted in to donation, their families should always be contacted for authorisation, regardless of how many years the student had been studying in Scotland.
- **Cultural / religious differences and language barriers:** Some respondents focused on the importance of giving due consideration to the cultural and religious views of people from different countries. It was also noted that 'foreign nationals' living in Scotland may not have sufficient English language skills to be aware of the requirement to opt out if they did not want their organs or tissue to be donated. It was suggested that advice should be sought from relevant foreign consulates in relation to the question of organ donation and there was a view that the application of deemed authorisation could, in certain circumstances, lead to 'diplomatic incidents'. There was also a suggestion that, unless it could be demonstrated that an individual had been given information in their own language about the opt out arrangements in Scotland,

then deemed authorisation should not apply regardless of how long the person had resided in Scotland.

- **Period of residence:** Some respondents commented on the timeframe of 12 months for explicit authorisation. Some wanted a longer timeframe for people who had moved to Scotland from elsewhere (up to 3 years was suggested), while others wanted a shorter timeframe (3 months was suggested).

7.21 Less often, respondents argued that the last category was irrelevant, that the residency check was unnecessary, and that deemed authorisation should apply for any individual (including a tourist) who died in Scotland. Some respondents commented that they personally had opted in to the ODR in Scotland, and so would wish and expect that if they died while travelling overseas that their organs should still be donated. Others noted that if an overseas student, migrant or other visitor to Scotland had opted in to organ donation in their own country, that this explicit authorisation should be respected if they died in Scotland.

7.22 There were also suggestions that any change in the law in this area would require a mechanism for proactively informing all new Scottish residents about the need to explicitly opt out if they do not want their organs or tissue to be donated. Any Code of Practice developed for an opt out system should take account of a more mobile population.

7.23 Finally, respondents also noted the implications and potential for confusion resulting from different legislation on organ and tissue donation in the different countries of the UK.

Other groups for whom explicit authorisation should be required

7.24 Some respondents suggested additional categories of people for whom explicit authorisation should also be required, or they queried whether explicit authorisation would be required for these groups:

- People who are disabled from birth who cannot make a decision for themselves
- People with learning disabilities who may have the capacity to make some decisions, but not fully understand the concept of organ donation
- Looked after children
- People with certain religious beliefs (e.g. those opposed to blood transfusions, etc.)
- People who are not voluntarily resident in Scotland (e.g. prisoners, or members of the armed forces stationed in Scotland)
- People who are not UK citizens with permanent residency status in Scotland.

Other views

7.25 A view – expressed much less often – was that there should be no excepted categories, and that deemed authorisation should apply in all cases.

Adults with incapacity (Q7)

7.26 As noted in paragraph 7.2 (first bullet point) above, it was proposed that deemed authorisation provisions should not apply in relation to adults who, over a period of time before their death, did not have capacity to take a decision on donation. Question 7 of the consultation was an open question which invited views about the circumstances in which an

adult should be viewed as not having the capacity to make their own decisions about donation.

7.27 Altogether, 610 respondents replied to this question – 28 organisations and 582 individuals – and there was a great deal of consistency in the comments made.

7.28 The most common view was that the Adults with Incapacity (Scotland) Act 2000 should provide the basis for decisions regarding capacity – and that the rules for determining capacity to decide about organ and tissue donation should be the same as those used to determine capacity in other contexts (such as capacity to decide about medical treatment). Respondents often made reference specifically to the 2000 Act, while others referred to it indirectly, suggesting that anyone who had a legal guardian, or who had given another adult power of attorney over their affairs should be considered to be an adult with incapacity.

7.29 Occasionally, respondents referred to existing mental health legislation, and suggested that anyone who had been ‘cared for’, ‘detained’ or ‘sectioned’ under mental health legislation should also be considered to not have the capacity to make their own decisions about donation.

7.30 It was also relatively common for respondents to identify particular conditions or illnesses which, they considered, could affect an individual’s capacity to make their own decisions. These included, for example:

- Dementia and other similar illnesses (including Alzheimer’s disease)
- Severe learning disability (including co-morbid learning disability and autism)
- Serious mental illness (ranging from depression to schizophrenia)
- Neurological disorders (such Parkinson’s disease or multiple sclerosis)
- Brain injury or brain damage.

7.31 More generally, respondents suggested that ‘any form of cognitive impairment’, ‘severe mental disability’, being ‘not of sound mind’, or having ‘additional support needs’ were all circumstances in which a person should be viewed as not having capacity to make their own decision about donation. Others discussed the loss or lack of ability to communicate or to understand communication. Less often, respondents suggested that certain forms of physical disability may also constitute circumstances in which a person may be viewed as not having the capacity to make their own decisions.

7.32 While respondents generally agreed about the circumstances in which a person would be seen as lacking capacity, there were conflicting views about what should happen upon that person’s death with respect to organ and tissue donation.

7.33 Some respondents agreed with the proposal in the consultation paper that explicit authorisation should be sought from the individual’s family – or guardian, advocate, or person with power of attorney – in these circumstances.

7.34 However, other respondents commented that clarification was needed regarding this proposal. Specifically, they noted that if an adult was viewed as not having the capacity to make their own decision at the point at which an opt out system was introduced, then they should not be subject to deemed authorisation. However, some argued that once an opt out

system was introduced, if an individual had sufficient opportunity (over a period of years) to choose to opt out, but did not do so, then, if that individual subsequently lost capacity (due to an accident or illness much later in life), then it could be argued that deemed authorisation should apply. This would be consistent with current arrangements whereby a decision to opt in results in organs being donated even if a person subsequently loses capacity before they die. In such cases, the subsequent loss of capacity is considered to be irrelevant.

7.35 It was suggested that, whatever time frame is specified for the period of incapacity before a person's death, that there is flexibility and that medical professionals have the discretion to decide whether, in particular circumstances, explicit authorisation should be required.

7.36 Others expressed concern about this proposal, noting that an individual's capacity may fluctuate throughout their life, and may be specific to certain tasks or types of decisions. These respondents commented that an opt in system was preferable for this reason, as it would be more straightforward to determine the wishes of an individual who may lack capacity at the time of their death.

7.37 There were also two less common opposing views: (i) that there are no circumstances in which a person with incapacity should require explicit authorisation from a family member or other individual; and (ii) no organs should be taken from an individual who lacks capacity at the time of their death under any circumstances.

Age at which deemed authorisation would apply in children (Q8)

7.38 In the current opt in system, children aged 12 and over are able to self-authorise donation. If there is no self-authorisation in place when the child dies, a parent may be asked if they wish to authorise. For children under 12 the donation can only proceed with parental authorisation. The consultation sought views on the age at which deemed authorisation should apply to children if an opt out system is introduced. Question 8 asked 'Under what age do you think children should only be donors with explicit authorisation?'

7.39 Altogether, 795 respondents replied to this question – 29 organisations and 766 individuals. Of these, the largest proportion of both organisational and individual respondents thought that explicit authorisation should be required for all children under 16 (either through self-authorisation or parental authorisation), and that deemed authorisation should apply for young people aged 16 and above. Around half of organisations and two-fifths of individuals expressed this view (Table 7.2).

Table 7.2: Q8 – Under what age do you think children should only be donors with explicit authorisation?

Respondent type	under 12	under 16	under 18	Other	Total
NHS and / or local authority	3	5	–	1	9
Professional groups and regulatory bodies	–	5	–	1	6
Charity, voluntary sector or patients' rights groups	1	5	2	–	8
Faith groups	–	–	1	5	6
Organisation (total)	4	15	3	7	29
Organisation percentage	14%	52%	10%	24%	100%
Individual respondents	296	319	87	64	766
Individual percentage	39%	42%	11%	8%	100%
Total (organisations and individuals)	300	334	90	71	795
Total percentage	38%	42%	11%	9%	100%

7.40 Among organisational respondents, views differed between faith groups and other organisations on this matter. Most of the faith groups selected 'other' in response to this question, while 15 of the remaining 23 organisations selected 'under 16'.

7.41 Table 7.2 shows that a relatively large proportion of individual respondents (39%) selected 'under 12' in response to this question. However, it is possible that the wording of the question and the explanation given in the consultation paper may have resulted in misunderstanding among some individual respondents. Those who offered further comments in response to this question often appeared to be discussing the age at which a child should be able to self-authorise, rather than the age at which deemed authorisation should apply. Thus, the figures shown for individual respondents in Table 7.2 should be treated with caution.

7.42 If respondents ticked 'other' in response to Question 8, they were invited to specify an age at which deemed authorisation would apply for children. Altogether, 116 respondents provided further comment. Note, however, that this figure includes 11 (mostly organisational) respondents who did not tick any of the choices offered at Question 8, and 34 respondents who ticked one of the first three choices. The comments of this latter group are summarised briefly below at paragraph 7.48. However, the main focus in the discussion below is on those who ticked 'other' or who did not tick any of the options at Question 8.

Views of those who favoured an 'other' threshold age for deemed authorisation

7.43 As mentioned above, respondents' comments indicated that there may have been some misunderstanding of Question 8. Respondents often discussed the age at which a child could be seen as having the necessary maturity to make decisions about organ donation, and whether a parent should (or should not) have the right to overturn a decision taken by a child to opt in. Therefore, if respondents suggested a particular age, it was not always clear whether they intended this to be: (i) the age at which a child could self-authorise; (ii) the age at which a child could self-authorise without parental authorisation and despite parental objection; or (iii) the age at which deemed authorisation should apply for a child.

7.44 Notwithstanding this lack of clarity, there was nevertheless a range of views on this issue. At the two extremes, there were some who thought that all children from birth should automatically be deemed donors unless explicitly opted out by the child or the child's parents

and, at the other end of the scale, those who thought that there should be no organ donation by children at all. The views of most respondents, however, lay somewhere between these two stances, and there was a general agreement that children should have the choice and opportunity to opt in. Respondents argued that the age at which this is appropriate may vary from one child to another. While it was generally thought that 12 years was reasonable, there were also suggestions that children of almost any age could make this decision if they were given appropriate information and support. Less commonly, respondents suggested that children should only be able to opt in at a later age (14, 16 or 18), or they argued that it was not possible to specify an age for self-authorisation given the wide variability in maturity and understanding that there may be among children of the same age.

7.45 There was disagreement between respondents about:

- **The age up to which parental authorisation should be required:** The most common view was that parental authorisation (in effect, allowing parents to overrule a child's decision) should be required up to age 16; however some respondents argued that it should be required up to age 18, 21 or 25).
- **The age at which deemed authorisation would apply:** The most common view was that deemed authorisation should apply from age 16; however, views ranged from 'deemed authorisation should apply for all children' to 'deemed authorisation should never apply'.

7.46 Some respondents suggested, more generally, that the threshold age for deemed authorisation should be consistent with other age limits for decision making by children. In relation to this point, it was noted that the Age of Legal Capacity (Scotland) Act 1991 confers legal capacity on children from the age of 16, but also allows under-16s to consent to medical treatment where the child is deemed by a qualified medical practitioner to understand the nature and possible consequences of treatment. However, as mentioned above (paragraph 7.16, point 2), it was also noted that in the Welsh legislation, the age threshold for deemed authorisation was 18.

7.47 Respondents raised a number of other relevant points in their discussions of this issue. These points were mostly raised by organisational respondents who had not ticked one of the boxes at Question 8:

- If the legislation changes with respect to organ and tissue donation and a soft opt out system is introduced, this legislation should take into account that the nearest relative for a young person aged 16 might be a spouse, and not a parent.
- The nature of organ and tissue donation by children may be slightly different to that of adults. For example, it was noted that children as young as 32 weeks gestation could donate heart valves, those from age 2 could donate corneas, etc.
- A great deal of effort has been made in Scotland to teach young adults about organ donation. As a result, it was noted that Scotland has the highest proportion of young people under 18 on the ODR in the UK.
- In relation to other medical treatment, a young person who has the ability to consent (or opt in) to a straightforward, relatively risk-free treatment may not necessarily have the capacity to consent to complex treatment involving high risks with potentially

serious consequences. Their ability to consent may also be affected by physical and emotional development, and by changes in their health or treatment.

- It was important that the implications of the United Nations Convention on the Rights of the Child were considered, and that children were supported in the process of exercising their rights and making their views known.

Views of respondents who selected 12, 16 or 18

7.48 This group of respondents was not invited to give further comment; nevertheless, some among this group did so. Again, it was apparent in the comments that some respondents may not have understood that the question was asking about the age at which deemed authorisation should apply in an opt-out system.

7.49 Organisational respondents, however, did generally make explicit reference to the issue of deemed authorisation, stating that age 16 (as proposed in the consultation paper) was appropriate. Respondents gave the following reasons in support of their views:

- The legal age of capacity in Scotland (i.e. the age at which people are treated as adults with regard to consenting to medical treatment) is age 16
- Children below the age 16 were unlikely to be aware of, and understand, the deemed authorisation requirements.

7.50 Three other main themes in these comments related to:

- **The role of the family:** A range of views were expressed including that: (i) a child's choice to opt in at age 12 should be respected even if a parent objected; (ii) a child should be able to donate their organs at any age with parental consent; and (iii) a child (up to 12, 16 or 18) should ONLY be able to donate their organs with parental consent.
- **Capacity of a child to understand about organ donation:** Most often, respondents discussed this issue in relation to the age at which a child should be able to self-authorise. While some thought a child of almost any age could understand about organ donation if it was properly explained – and so should be given the right to self-authorise – others thought that safeguards should be built in to ensure that, if a child opts in to the ODR, they understand the implications of this. There was also a suggestion that the 'Fraser–Gillick guidelines could apply'.⁶
- **Circumstances in which deemed authorisation could be set at age 12:** Finally, there was a view that the age at which deemed authorisation would apply could potentially be set at age 12 if all pupils received information through schools about donation and how it applies to them prior to this age.

Authorising organ and tissue donation for looked after children (Q9)

7.51 The consultation paper explained that, where decisions about organ donation were made on behalf of children, it would be the child's parent(s) or another person with parental

⁶ Gillick competency and Fraser guidelines refer to a legal case in 1982 which looked at whether doctors should be able to give contraceptive advice or treatment to children under 16 without parental consent. They have since been more widely used to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions.

responsibilities and rights who would decide. Under current legislation, if a child is looked-after, the local authority with parental responsibility cannot currently authorise donation if no parent is available. It was suggested, however, that this restriction could be reconsidered, and it was noted that in England and Wales, local authorities may authorise donation for children in their care if no parent is available. The consultation (Question 9) asked respondents for their views on this issue.

7.52 Altogether, 804 respondents addressed this question – 28 organisations and 775 individuals. The largest proportion of both organisational and individual respondents thought that local authorities should be able to authorise donations in these circumstances. However, a relatively large minority of both groups (25% and 29%, respectively) thought that local authorities should **not** be able to authorise donations in these circumstances. Moreover, among organisations, respondents were more likely to **either** disagree **or** indicate uncertainty in response to this question than to indicate support (Table 7.3).

Table 7.3: Q9 – For children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available?

Respondent type	They should be allowed to authorise donation of a child's organs or tissue in those circumstances	They should not be allowed to authorise donation of a child's organs or tissue	Don't know	Total
NHS and / or local authority	4	2	5	11
Charity, voluntary sector or patients' rights groups	5	–	2	7
Professional groups and regulatory bodies	3	2	–	6
Faith groups	1	3	1	5
Organisation total	13	7	8	28
Organisation percentage	46%	25%	29%	100%
Individual respondents	445	227	103	775
Individual percentage	57%	29%	13%	100%
Total (orgs and individuals)	458	234	111	804
Total percentage	57%	29%	14%	100%

7.53 Question 9 was a closed question, with no follow-up question inviting respondents to provide further details about their views. However, four individual respondents included comments at Question 15 in relation to this question, and 11 of the organisational respondents who submitted their responses by email also provided comments. Five of these organisational respondents did not select any of the response options offered at Question 9, and their views on this question could not be inferred. Of the five NHS / local authority respondents who offered comments, three answered 'don't know' in response to this question and two did not tick any of the boxes.

7.54 The comments made by organisations in relation to this question often indicated qualified support – i.e. support with caveats.

Views of NHS / local authority organisations

7.55 NHS / local authority organisations thought that if the law were changed to permit a local authority to authorise donation on behalf of a child in care where the parent is deceased or absent, such authorisation should only occur if the following conditions were met:

- The person giving the authorisation would need to know the child well – to ensure that donation is something that they or their family would not have opposed, but also to be able to provide the necessary information to ensure that the donation was safe.
- If the child has any living relatives, they should be involved in the donation process where possible and appropriate.
- The local authority should have clear documentation that neither the child nor the family had previously expressed wishes against donation.

7.56 A slightly different perspective was voiced by the (one) health and social care partnership which offered comments on this question. This respondent thought that:

- If a local authority is acting as defacto parent for a child, the law should be applied in the same way as for any other parent.
- There should **not** be an expectation that local authorities should ask every child or young person in the care what their preferences would be in relation to organ and tissue donation, nor should there be a requirement that this information is recorded and kept up-to-date. There was a concern about the potential for significant and unjustified bureaucracy to be created.
- Rather than giving the local authority the responsibility to make a decision on a case by case basis, it should be stated explicitly in the legislation what should happen in the cases of children in care.

Views of professional groups and regulatory bodies

7.57 Five professional groups / regulatory bodies offered comments. In three of these cases, the respondent indicated that local authorities should be allowed to authorise organ donation on behalf of a child where the parent is not available. This group made the following suggestions:

- The process for authorising donation of organs from a child who had died in care should not be the sole responsibility of any one local authority employee.
- Appropriate training should be provided to local authority staff to enable them to fulfil this role.
- Where a child had chosen to opt in, the local authority should take steps to facilitate the child's wishes.
- While local authorities should not be prohibited from authorising organ and tissue donation from a child who had died in care, it was accepted that donations may not necessarily proceed, and that those decisions should be taken by the relevant specialist organ donation team.
- Older siblings, grandparents or other close relatives could be asked to provide the required authorisation if the child's parents are not available. Moreover, the position of

long term carers who hold parental responsibilities and rights under a permanence order should also be considered.

- If the intention is to give local authorities the power to authorise donation on behalf of a child where a parent is unavailable, it is important to be clear about the definition of 'unavailable'.

7.58 The point was also made that there may be other circumstances where local authorities could be called upon to make decisions about donation which relate to children who are **not** 'looked-after' – for example where a child was with his parents in a car accident, and although the parents have survived, they may not (temporarily) be able to authorise donation.

Views of other respondents

7.59 Among the very few other respondents who commented on this issue (four individuals, and two organisations), the following points were made, some of which echoed those discussed above:

- If a child has opted in or out of the ODR, their wishes should be respected if they die while in local authority care.
- If the child has not self-authorized and is under the age of 16, decisions about organ donation should be scrutinised through a full Child Rights and Wellbeing Impact Assessment (CRWIA) to ensure that the decision is consistent with the UN Convention on the Rights of the Child.
- The person(s) making the decision about organ donation for a child in care should be someone who knows the child well – a foster parent or a member of staff in the care home / school which they are resident in.
- Safeguards should be put in place for local authorities when making such decisions. This might include the involvement of a legal professional.
- If the child has a particular religious or ethnic background, the decision to authorise donation should be taken only after discussion and agreement with leaders / authorities in the relevant community.

8. Donations of less common types of organs or tissue (Q10)

8.1 This chapter discusses respondents' views regarding provisions for donation of less common types of organs and tissue. Examples of such donations, as discussed in the consultation paper, included the donation of limbs and facial tissue.

8.2 The consultation paper proposed that under a soft opt out system, deemed authorisation would apply to donation of the more common types of organ and tissue: kidneys, liver, pancreas, heart/heart valves, lungs, small bowel and stomach, tendons, skin, corneas and bone. Views were sought about whether deemed authorisation should also apply to 'more rare or novel types' of tissue or organs – or whether explicit authorisation (from the donor themselves or their family) should be required in relation to these types of donations.

Question 10: In any opt out system, what provisions do you think should apply to the less common types of organs and tissue? [Deemed authorisation provisions should apply to all organs and tissue / Deemed authorisation provisions should only apply to the more common organs and tissue]

8.3 Question 10 was a closed question with no space for additional comment. However, a small number of the organisational respondents provided comments in emailed responses or at Question 15 in the online questionnaire. These comments are discussed briefly below.

8.4 Altogether, 774 respondents replied to Question 10 – 28 organisations and 746 individuals. Organisational respondents were divided in their views about whether deemed authorisation provisions should apply to **all** organs and tissue, or only the more common organs and tissue. A small majority (54%) thought it should apply only to the more common organs and tissue. By contrast, most individual respondents (83%) were in favour of deemed authorisation provisions applying to **all** organs and tissue (Table 8.1).

Table 8.1: Q10 – In any opt out system, what provisions do you think should apply to the less common types of organs and tissue?

Respondent type	Deemed authorisation provisions should apply to all organs and tissue	Deemed authorisation provisions should only apply to the more common organs and tissue	Total
NHS and / or local authority	6	5	11
Charity, voluntary sector or patients' rights groups	4	4	8
Professional groups and regulatory bodies	2	4	6
Faith groups	1	2	3
Organisation total	13	15	28
Organisation percentage	46%	54%	100%
Individual respondents	618	128	746
Individual percentage	83%	17%	100%
Total (orgs and individuals)	631	143	774
Total percentage	82%	18%	100%

8.5 Four organisations offered further comments to explain their views. Three of these thought that deemed authorisation should only apply to the more common organs and tissue, noting that this would be consistent with the current Welsh legislation. This group of respondents commented that certain forms of transplantation may be expected to have a greater emotional impact on family members and the general public, and they suggested that:

- The less common organs and tissue (not subject to deemed authorisation) should be set out in Regulations so that the list can be updated as and when new options become available.
- The restrictions should be widely publicised, as media coverage of such transplants may result in people choosing to opt out if they (mistakenly) believe deemed authorisation would apply to these types of organs or tissue.
- People should be given the opportunity to selectively opt out of some forms of donation if they wish to do so.
- There should be explicit authorisation for donation for research purposes.

8.6 One organisation was in favour of deemed authorisation applying to all organs and tissue 'for practical reasons'.

9. Pre-death tests and treatments for potential donors (Q11 – Q13)

9.1 This chapter presents an analysis of respondents' views in relation to the proposals set out in the consultation paper about pre-death tests for potential donors.

9.2 The consultation paper noted that if a soft opt out system were introduced, it was necessary to determine whether deemed authorisation of donation should (or should not) allow certain tests to be carried out on a potential donor to help facilitate the donation in cases of Donation after Circulatory Death (DCD). If such tests were not allowed, or if they were only permitted with explicit authorisation from the patient or their family, then this would in most cases prevent successful organ donation from proceeding, even in cases of deemed authorisation.

9.3 If it were agreed that such tests could proceed, they would be carried out before life-sustaining treatment was withdrawn from a DCD patient. The tests proposed were the following:

- Blood tests (for tissue typing to find a good recipient match, to identify any infections, and to test the patient's blood gases to check lung function)
- Urine tests (to check for infections)
- X-rays (to check for any undiagnosed medical problems)
- Tests on a sample of chest secretions (to test lung function)
- Tests on the heart (to check heart function).

9.4 Respondents were asked for their views in relation to all five of these tests. Two further follow up questions were also asked. First, if respondents answered 'no' regarding any of the five proposed tests, they were then asked if there were any circumstances when particular tests could be permitted. Second, all respondents were asked whether it should be permitted – if a potential donor's condition is unsurvivable and it will not cause them discomfort – for medical staff to provide medication to improve the chances of their organs being successfully transplanted.

Question 11: Which tests do you think medical staff should be able to carry out on a potential donor before they withdraw life-sustaining treatment? Blood tests? Urine tests? X-rays? Tests on a sample of chest secretions? Tests on the heart? [Yes / No / Don't know]

Question 12: If you answered no to some or all options in Question 11, are there any circumstances when particular tests could be permitted? [If the person had previously made clear they wished to be a donor / If the donor's family provided consent on the donor's behalf / Such tests should never be permitted before death]

Question 13: Where it is agreed a patient's condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given?

Views on pre-death tests (Q11 and Q12)

9.5 In relation to Question 11, between 789 and 795 respondents replied in relation to each of the five proposed tests. In every case, the vast majority of respondents agreed that such tests should be able to be carried out. The proportion of respondents agreeing ranged from 84% to 93% (See Table 9.1 below).

Table 9.1: Q11 – Which tests do you think medical staff should be able to carry out on a potential donor before they withdraw life-sustaining treatment?

	Organisations		Individuals		Total	
	n	%	n	%	n	%
Blood tests?						
Yes	24	86%	717	93%	741	93%
No	2	7%	34	4%	36	5%
Don't know	2	7%	17	2%	19	2%
Total	28	100%	768	100%	796	100%
Urine tests?						
Yes	25	89%	696	91%	721	91%
No	1	4%	36	5%	37	5%
Don't know	2	7%	31	4%	33	4%
Total	28	100%	763	100%	791	100%
X-rays?						
Yes	24	86%	639	84%	663	84%
No	1	4%	62	8%	63	8%
Don't know	3	11%	60	8%	63	8%
Total	28	100%	761	100%	789	100%
Chest secretions?						
Yes	25	89%	689	90%	714	90%
No	1	4%	42	5%	43	5%
Don't know	2	7%	36	5%	38	5%
Total	28	100%	767	100%	795	100%
Tests on heart?						
Yes	24	86%	695	91%	717	91%
No	1	4%	40	5%	41	5%
Don't know	3	11%	30	4%	33	4%
Total	28	100%	765	100%	793	100%

Circumstances in which pre-death tests could be permitted (Q12)

9.6 Altogether 66 respondents (1 organisation and 65 individuals) answered 'no' in relation to one or more of the tests listed above. These 66 respondents were then asked (in Question 12) whether there were any circumstances when particular tests could be permitted. Just over half (53%, 35 out of the 66) said that tests could be permitted if the person had previously made it clear that they wished to be a donor. The next most common view among this group, indicated by almost a third (29%, 19 out of 66) was that such tests should never be permitted before death (Table 9.2).

Table 9.2: Q12 – If you answered no to some or all options in Question 11, are there any circumstances when particular tests could be permitted?

Respondent type	Organisations	Individuals	Total	%
If the person had previously made clear they wished to be a donor	1	34	35	53%
Such tests should never be permitted before death	–	19	19	29%
If the donor's family provided consent on the donor's behalf	–	12	12	18%
Total	1	65	66	100%

Views relating to pre-death tests

9.7 A small number of respondents (18) provided comments in relation to carrying out pre-death tests on potential donors. In the main those commenting were organisations that were broadly in favour of an opt out system and content for tests to be carried out. Some respondents offered reasons for their views indicating that they saw authorisation of organ donation – explicit or deemed – as including authorisation to carry out any care which would facilitate a successful donation; and that the proposed tests were ‘standard practice’, and justified given the minimal harm involved and likely benefit achieved. More often, however, respondents offered qualifications to their agreement to pre-death tests being carried out, and made the following points:

- That the conduct of pre-death tests should be done with full respect for the potential donor and their family
- That families should be informed of the test(s) to be carried out and / or they should only be carried out with family consent
- That tests should be carried out sensitively, within set limits and with minimal invasion and interference with the individual (e.g. the test should not require moving the patient)
- That the possibility of pre-death tests being carried out should be covered in an appropriate way in public information about any opt out system.

9.8 It was also suggested that any ‘rules’ in this respect would have to be based on principles, with the option of updating to reflect changes in medical practices, and that thought would have to be given to the ethical considerations of carrying tests for conditions including infectious diseases such as HIV, which may have implications for family members.

9.9 There were a few comments from respondents who were opposed to or had reservations about carrying out pre-death tests. Their opposition was linked to general concerns about an opt out system, and they thought that pre-death tests should only proceed within the context of an opt in system and / or where the individual had given explicit consent to the test. There was also a specific concern about the impact on grieving families, and the possibility that increased distress may lead to the withdrawal of consent.

9.10 Additionally, a few respondents highlighted the need for any proposals for pre-death tests to be considered alongside other existing legislation and protocols (e.g. the Adults with Incapacity (Scotland) Act 2000; the Organ Donation and the Emergency Department Strategy).

Provision of transplant-related medication before death (Q13)

9.11 Question 13 asked respondents to consider whether medication could be administered to a patient before their death to improve the chances of successful transplantation – if their condition is unsurvivable and the treatment would not cause them discomfort.

9.12 Altogether, 798 respondents replied to this question – 27 organisations and 771 individuals. Both organisational and individual respondents generally agreed that medical staff should be able to provide such treatment to a donor to improve the chances of a successful transplant. However, two of the three faith groups and one of the five professional / regulatory bodies responding to this question thought that treatment just to help the donation should **not** be permitted (Table 9.3).

Table 9.3: Q13 – Where it is agreed a patient’s condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted?

Respondent type	They should be able to provide such forms of treatment	They should be able to provide such treatment, but only where the donor’s family provides consent	They should not be able to provide any such treatment just to help the donation	Total
NHS and / or local authority	9	2	–	11
Charity, voluntary sector or patients’ rights groups	5	3	–	8
Professional groups and regulatory bodies	3	1	1	5
Faith groups	1	–	2	3
Organisation total	18	6	3	27
Organisation percentage	67%	22%	11%	100%
Individual respondents	556	156	59	771
Individual percentage	72%	20%	8%	100%
Total (orgs and individuals)	574	162	62	798
Total percentage	72%	20%	8%	100%

9.13 Again, this was a closed question with no space for further comment. Those who did comment (one individual and eight organisations) did so within offline responses, or at Question 15 in the online questionnaire. The points made were similar to those at Questions 11 and 12, with respondents largely noting caveats and qualifications to their support for the proposal, in particular: the need to prioritise the welfare of the patient and the family; the need to inform the family and ensure they understood the treatment being proposed; the need for any treatment to be carried out in accordance with existing guidelines and practices; and the need for some treatments to only be given once progression to death was certain.

9.14 Those expressing opposition or reservations had ethical concerns about carrying out treatment on one person for the benefit of another, or which extended the life of someone who was not going to survive, particularly within an opt out system. The importance of compatibility with existing legislation and practices was also again noted.

10. Involvement of authorised representatives (Q14)

10.1 This chapter discusses respondents' views on the option to allow people to nominate a representative (or proxy) to make decisions for them about donation when they die. It is currently possible to do this in England and Wales, but not in Scotland.

10.2 The consultation paper noted that if a person is capable of nominating a representative to make this decision for them, then, in most cases, the individual would also be able to decide for themselves whether or not they wished to donate (and could register that preference). Thus, it was unlikely that such a representative would be needed. Involving proxies in the decision-making process could also result in making the process more complex and lengthy. Finally, it was noted that very few people in England and Wales had appointed such a representative as of 31 March 2016, and that they had not yet ever been used. Therefore, the Scottish Government proposed not to include provision for authorised representatives in any revised legislation; however, respondents were invited to give their views on this issue.

Question 14: What do you think about allowing people to appoint one or more authorised representatives to make decisions for them? [This should be allowed / This is not necessary / Don't know]

Question 14a: If you think this should be allowed, in what circumstances do you think an authorised representative would be useful?

10.3 Altogether, 804 respondents answered Question 14 – 33 organisations and 771 individuals. There were different views among organisations and individuals about whether people should have the option to appoint one or more authorised representatives to make decisions for them about donation when they die. A small majority of organisations (52%) said that this is not necessary, while a small majority of individuals (53%) said that this type of proxy authorisation should be allowed (Table 10.1).

Table 10.1: Q14 – What do you think about allowing people to appoint one or more authorised representatives to make decisions for them?

Respondent type	This should be allowed	This is not necessary	Don't know	Total
NHS and / or local authority	4	6	2	12
Charity, voluntary sector or patients' rights groups	3	4	1	8
Professional groups and regulatory bodies	3	4	–	7
Faith groups	3	3	–	6
Organisation total	13	17	3	33
Organisation percentage	39%	52%	9%	100%
Individual respondents	412	269	90	771
Individual percentage	53%	35%	12%	100%
Total (organisations and individuals)	425	286	93	804
Total percentage	53%	36%	12%	100%

10.4 If respondents indicated that provision for authorised representatives should be allowed, they were asked a follow-up question about the circumstances in which an authorised representative might be useful.

10.5 Altogether, there were 305 responses to this question. This includes 33 from those who answered 'this is not necessary', 12 from those who answered 'don't know' and two who did not tick any of the choices at Question 14. The comments made by these latter groups are discussed at the end of this section. However, the comments of those who thought that authorised representatives should be allowed are discussed first.

Circumstances in which an authorised representative might be useful

10.6 Respondents identified a range of circumstances (some of them discussed in the consultation paper) where an authorised representative might be useful. These included:

- Where an individual was in unstable social circumstances (e.g. breakdown in family relationships; a child in and out of local authority care; those in long term hospital care; where the individual has no family; those in custody; etc.)
- Where the individual was an adult with incapacity – however, some respondents commented that Power of Attorney arrangements could (and may already, in some cases) fulfil this purpose
- Where they would prefer not to burden their family with the decision about donation
- Where they believe their family is likely to oppose their wishes to donate.

10.7 This group of respondents also identified some benefits of appointing a proxy for this purpose:

- **It would provide peace of mind to the donor:** Having an authorised representative might be particularly important for certain ethnic or religious communities. For example, some groups may have no objection to organ or tissue donation, and may choose to opt in, but would have very specific concerns about the manner in which the organs were removed from the body. Having an authorised representative to communicate those issues and ensure that the donation was carried out in the correct manner would be helpful.
- **The authorised representative would be someone trusted by the donor:** Some respondents thought that there could be cases where an individual did not feel comfortable making a decision about organ donation themselves, and so had not expressly opted in or out (thus a deemed authorisation situation). In such cases, or in any case where the individual had not made their wishes clear, it might be preferable to have someone other than a family member, who was trusted by the individual, to make the decision for them.
- **Helps to clarify the person's wishes:** Other respondents thought that the process of appointing a proxy would in itself help the individual to clarify their own wishes.

10.8 The following views were also expressed by respondents in this group (usually by just one or two individuals):

- In relation to the mechanism for appointing an authorised representative, there was a view that any individual taking on this role must be explicitly and legitimated appointed and authorised by the individual to ensure there is no uncertainty at the time of the individual's death. However, there was also an alternative view that the arrangement could be a rather informal one based on verbal instruction alone.
- Part of the role of the authorised representative should be to ensure that the deceased person was aware of the authorisation system, had not objected to having his / her organs donated, and had recently shared their wishes with the authorised representative.
- There may be benefit in allowing people to appoint two representatives (as in England and Wales).

Views of other respondents

10.9 Respondents who thought that the provision of authorised representatives was not necessary, who did not know if it was necessary, or who did not indicate a view made the following points:

- Some had no objection in principle in allowing people to appoint authorised representatives, but agreed with the consultation paper that it was likely to be an unnecessary and potentially very time-consuming complication.
- A concern about providing for the nomination of authorised representatives is that it potentially complicates messages to people about how the opt out system would work. There was a view that in order for an opt out system to work, the messages to people must be clear and must be able to be understood.
- There were concerns about the possibility of representatives being chosen, and then relationships changing over a number of years, without the relevant paperwork being updated.
- Some believed that, irrespective of whether a person had appointed a representative, medical staff would still wish to involve the person's family in the decision, and where there was conflict between the two, it was unlikely that the donation would proceed.
- Some respondents commented that they could not form a view on this question without further information about how the use of authorised representatives would work in practice.

10.10 There was also a general view among this group that if a person had the ability to appoint a representative to make this decision for them, they should simply make the decision in their own terms by expressly opting in or opting out. Some were unclear about the purpose of such a representative if an individual had expressly made their wishes known. Some went further and argued that in an opt out system, the burden of responsibility for opting out lies entirely with the individual, and other individuals (whether appointed representatives, or family members) should not be able to prevent a donation going forward.

11. Health service practices (Q16 and 17)

11.1 This chapter discusses respondents' views about two possible initiatives which could increase the number of people considered as organ or tissue donors by influencing practice within health care settings. These initiatives were: (i) the issuing of Chief Medical Officer (CMO) guidance to encourage clinicians to refer dying or recently deceased patients for consideration as potential organ or tissue donors, and (ii) the introduction of a requirement to involve specialist staff in discussions with families about organ donation. Questions 16 and 17 invited views on these initiatives:

Question 16: What do you think about providing Chief Medical Officer (CMO) guidance to encourage clinicians to refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor?

Question 17: What do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?

Issuing of CMO guidance (Q16)

11.2 The consultation paper set out information and evidence on the current processes for considering potential organ donors, referral to specialist donation staff, and the incidence of 'missed' referrals (i.e. cases in which clinicians do not refer potentially suitable patients). Although referral rates have increased over recent years, Question 16 asked for views on whether CMO guidance might be helpful in bringing about further improvement.

11.3 A total of 792 respondents answered Question 16 – 760 individuals and 32 organisations – with almost nine out of ten agreeing that CMO guidance should be provided. (See Table 11.1.) Organisations were slightly less likely than individuals to agree with the proposal. Although only one organisation – a faith group – disagreed with the proposal, organisations were more likely to select 'other' and go on to explain their views.

Table 11.1: Q16 – What do you think about providing Chief Medical Officer (CMO) guidance?

Respondent type	CMO guidance should be provided	CMO guidance should not be provided	Other (please specify)	Total
NHS and / or local authority	10	–	2	12
Charity, voluntary sector or patients' rights groups	9	–	–	9
Professional groups and regulatory bodies	4	–	2	6
Faith groups	3	1	1	5
Organisation total	26	1	5	32
Organisation percentage	81%	3%	16%	100%
Individual respondents	670	57	33	760
Individual percentage	88%	7%	4%	100%
Total (organisations and individuals)	696	58	38	792
Total percentage	88%	7%	5%	100%

11.4 A total of 76 respondents – 59 individuals and 17 organisations – provided additional comments on Question 16.

11.5 Those who supported the issuing of guidance gave two main reasons for their views:

- They felt that it was important that cases were passed on to specialist staff as not all clinicians were well placed to make decisions about organ donation, and they thought that CMO guidance would provide clarity about the referral process and the role of specialist staff, and would support and encourage good practice in this area of work. The potential benefits of a clear 'trigger' for referral were noted.
- They believed that all healthcare staff had a role to play in supporting organ donation and transplantation, and in facilitating the wishes of potential donors. As such, they thought that CMO guidance could be useful in emphasising this role, raising awareness about organ donation among healthcare staff, and contributing to education and training among the workforce in general.

11.6 It was, though, common, for respondents to qualify their support for the issuing of CMO guidance. Comments focused on the 'framing' of any guidance; the possible impact on the overall approach to organ donation; and possible resource implications. On each of these, respondents made the following linked points:

- Most frequently respondents commented on the way the proposed guidance might be framed (e.g. in terms of referring '**almost all** dying or recently deceased patients for consideration as a potential organ or tissue donor'). They thought that any guidance should focus on ensuring that all appropriate cases were referred to specialist staff. The guidance, therefore, needed to be framed in such a way as to allow clinical staff to consider the circumstances in any individual cases and exercise professional judgement in deciding whether to make a referral. It was argued that to do otherwise would place unreasonable demands on healthcare resources (specialist staff, ITU staff and facilities, etc.), and would also increase stress on families as not all cases would ultimately prove suitable for donation.
- Respondents were also concerned that CMO guidance did not unintentionally bring about a shift in the general approach towards organ donation. They stressed that the guidance should continue to respect the rights of individuals to make their own decisions about organ donation and should not result in pressure being put on individuals or families by suggesting a presumption in favour of donation. Respondents were clear that families should continue to be dealt with sensitively – a specific suggestion was that referrals should only be made after families had been made aware of a terminal prognosis.
- Additionally respondents were concerned about the resource implications of complying with CMO guidance. As noted above, some respondents were concerned that inappropriate referrals would increase the burden on specialist and non-specialist staff and facilities, and would represent a waste of resources; others simply called for any new guidance to be appropriately resourced.

11.7 In addition, a few respondents who nevertheless indicated support for the idea of CMO guidance also queried (i) whether it was really required given existing good practice in this area, and (ii) the impact the guidance would have.

11.8 A number of more specific suggestions were made by those who supported the introduction of CMO guidance. These included that:

- The guidance should be part of a wider package of measures designed to facilitate organ donation.
- Written guidance should be accompanied by visible CMO leadership on this issue.
- Individual staff should be given the right to opt out of the referral process.
- The guidance should be publicised so that families would be aware of practice.
- The impact of any guidance – on the number of successful donations made and on the ‘ethos’ of the organ donation system – should be monitored, and that non-referrals should be reviewed so that lessons could be learned at a local level.

11.9 Those who did **not** think CMO guidance should be issued often made very similar points to those made by those who supported the guidance. For this group, however, the qualifications noted above were articulated as reasons why guidance should not be introduced. The following points were particularly emphasised by this group:

- They felt that the proposed CMO guidance was unnecessary or unhelpful. They thought that effective good practice was already followed in relevant healthcare settings, or that it would be inappropriate to refer all (or nearly all) cases. These respondents stressed the importance of exercising professional judgement – taking account of the full medical and family circumstances – in making referrals, and that any guidance which required or encouraged additional referrals would risk undermining trust in the transplant system, and would place an unnecessary burden on specialist resources.
- They had ‘ethical’ concerns about the guidance, suggesting that it could give too much power to the medical profession, put pressure on families and undermine the principle of organ donation as a voluntary ‘gift’. These respondents were keen that a personal decision not to sign up to the ODR should be respected. It was also suggested that the introduction of guidance could in fact be counterproductive in alienating both healthcare staff and members of the public.
- They were concerned that adhering to the guidance would represent a poor use of resources for minimal gain.

11.10 However, among those who did not think that CMO guidance should be issued, there were some who made it clear that they did not support the guidance as described in the consultation paper – this group argued instead for more focused guidance which would target cases involving patients who were on the ODR or cases where donation was a realistic prospect.

11.11 Around half of those commenting on this proposal did not indicate clear support for or opposition to the proposal (this includes respondents who ticked ‘other’ at Question 16). The points made by this latter group largely reflected the qualifications and concerns highlighted by those indicating support or opposition to the issuing of CMO guidance, and are therefore covered in the sections above. A small number of additional points were, however, made by this group, as follows:

- The proposed guidance was addressing the wrong issue – CMO guidance would be better directed at encouraging healthcare professionals to encourage people to sign up to the ODR.
- The proposed guidance should not be necessary if hospitals had effective protocols and practices in place.
- Further evidence was needed about the scope to increase successful donations from missed referrals.
- The proposed guidance would not be practical in all settings (e.g. in the community, or in dealing with terminally ill cancer patients).
- The impact the guidance would have was unclear.

11.12 It should be noted that the comments made indicated that respondents had not all interpreted this question in the same way. In particular, some respondents thought the proposal presumed the continuation of an opt in system, while others thought it was intended to apply to a possible new opt out system for organ donation. Among this latter group of respondents, some were opposed to the guidance as they were opposed to an opt out system, while others did not think the proposal was relevant to an opt out system.

11.13 Finally, among individuals in particular, there was uncertainty about how such guidance would sit with either an opt in or opt out system, and what difference it would make.

Involving specialist staff in approaches to families (Q17)

11.14 The consultation paper presented information on the involvement of specialist staff in discussion with families about possible organ donation and noted the positive impact such involvement had on authorisation. Question 17 asked respondents for their views on whether it should be a requirement to involve specialist staff in approaches to families.

11.15 A total of 797 respondents – 765 individuals and 32 organisations – answered Question 17. Table 11.2 shows that around four-fifths of all respondents agreed that this should be a requirement, with a similar pattern of responses across both individuals and organisations. Among organisations, charities were unanimous in their support for the proposal, with a majority of all other types of organisations also indicating support.

Table 11.2: Q17 – What do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?

Respondent type	This should be a requirement	This should not be a requirement	Don't know	Total
NHS and / or local authority	8	2	2	12
Charity, voluntary sector or patients' rights groups	9	–	–	9
Professional groups and regulatory bodies	4	1	–	5
Faith groups	5	1	–	6
Organisation total	26	4	2	32
Organisation percentage	81%	13%	6%	100%
Individual respondents	596	96	73	765
Individual percentage	78%	13%	10%	100%
Total (orgs and individuals)	622	100	75	797
Total percentage	78%	13%	9%	100%

11.16 There was no open question asking respondents for additional comments on this proposal. However, a small proportion of respondents (around 20 in total), provided relevant comments at Question 16 or Question 15, and these comments form the basis of the analysis presented below. It should be noted that there was a good deal of cross-over in the comments made by those who agreed and those who disagreed with the proposal.

11.17 In general respondents who **supported** the proposal did so because they believed that involving specialist staff in discussion with families about organ donation increased the chances of authorisation being granted, and had a positive impact on the wellbeing of families. Some referred to evidence in support of this stance, while others said that doing this was in line with existing good practice, and with the recommendations of existing guidance, and that a new requirement would provide further reinforcement of this. It was also suggested that, while all staff had a responsibility to facilitate the wishes of a dying person, clinical staff were not always best placed to undertake sensitive discussions with families.

11.18 However, respondents often qualified their support for the proposal, as follows:

- The requirement would have resource implications which needed to be considered. In particular, it was suggested that the requirement should be accompanied by a duty for a SNOD to be available within a certain timeframe. Particular implications for more rural areas were also noted.
- The emphasis should be on involving a SNOD or other person with appropriate knowledge and training 'where feasible' – the fact that a SNOD was not available should not be seen as a reason for not discussing organ donation with families. (Other respondents, however, highlighted the apparent contradiction in having a 'requirement' which only needed to be fulfilled 'where feasible'.)

- The most appropriate person to be involved in discussions with the family would depend on circumstances but may not always be a SNOD or other organ donation specialist.

11.19 Those who did **not** support the introduction of a new requirement did not often comment on this issue specifically, but in most cases they voiced concerns about demands on SNOD staff. One respondent, however, argued that the evidence did not in fact show a positive link between SNOD involvement and family authorisation for organ donation – they referred to research carried out by John Radcliffe Hospital which found no increase in consent rates for organ donation when discussions with families were conducted by a clinician and a specialist as opposed to just a clinician.

Other comments

11.20 Across both Questions 16 and 17, there were a number of other more general points made. These included the following:

- That a package of measures was required to improve the health service infrastructure with regard to organ donation and transplantation
- That there were other, more important issues which might be addressed within the health service which would increase donation and transplantation rates – these included addressing the time it could take to process the offering and accepting of donated organs, and the variability in acceptance and refusal by individual transplant units, given that delays in confirming use can be a factor in withdrawal of family authorisation
- That it was important to learn from cases in which potential donors were not referred to specialist donation staff.

12. Equality impacts and implications (Q18)

12.1 The final question in the consultation paper focused on equality issues, as follows:

Question 18: Do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? [Yes / No / Don't know] If yes, please provide details.

12.2 A total of 791 respondents (758 individuals and 33 organisations) answered the tick-box question. Table 11.1 below shows a notably different response pattern for organisations and individuals. Just over half of the organisations who answered the tick-box question said that they could identify impacts or implications for particular equalities groups, compared to around a fifth of individuals. Individuals were more likely to say they could **not** identify such impacts / implications or that they did not know what the impacts or implications might be – roughly equal proportions of individuals (two in five) selected each of these responses.

Table 11.1: Q18 – Do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative?

Respondent type	Yes	No	Don't know	Total
NHS and / or local authority	3	6	1	10
Charity, voluntary sector or patients' rights groups	3	3	2	8
Professional groups and regulatory bodies	5	2	–	7
Faith groups	7	1	–	8
Organisation total	18	12	3	33
Organisation percentage	55%	36%	9%	100%
Individual respondents	135	302	321	758
Individual percentage	18%	40%	42%	100%
Total (orgs and individuals)	153	314	324	791
Total percentage	19%	40%	41%	100%

12.3 Comments were provided by 159 respondents – 138 individuals and 21 organisations (this included some who answered 'no' or 'don't know' to the tick-box question). In the main, respondents identified negative impacts and implications for one or more groups; some respondents did, however, identify positive impacts and implications. Additionally, it should be noted that the same groups were sometimes highlighted by different respondents in discussing anticipated positive and negative impacts.

Views on an opt out system and perceptions of equality impacts

12.4 The comments made suggested that there were differences in the way respondents answered the question on equality impacts depending on whether or not they supported an opt out system for organ donors. Those opposed to an opt out system were more likely to identify negative equality implications, and their comments suggested that the identified

impacts were seen as inherent problems with an opt out system. In contrast, those who supported an opt out system were more likely to identify positive impacts and implications and, where they identified negative impacts, they often stressed that the concerns relating to equality groups should be acknowledged and addressed through appropriate procedures and safeguards rather than seeing them as argument against such a system.

Negative impacts and implications

12.5 Respondents identified a wide range of groups they thought might be adversely affected under an opt out system. This included: (i) groups who may be opposed to the principle of opting out because of their beliefs; (ii) those needing additional protections because of their personal situations; and (iii) those less likely to be aware of an opt out system or less able to exercise their right to opt out.

12.6 Religious groups were the focus of most people's comments. In most cases respondents appeared to be raising this issue from a third party perspective; there were, however, a few respondents – including some faith organisations – who had a direct interest in the issue.

12.7 Most respondents raised general concerns only, noting that an opt out system for organ donation may be problematic for some religious groups. Those who offered more detailed comments identified three main issues: that some people may be opposed in principle to organ donation and / or transplantation for religious or cultural reasons; that religious or cultural requirements relating to the handling and burial of the deceased may need to be considered; and that the issue of explicit consent was crucial for some who believed in the sanctity of the human body and human autonomy. Respondents argued that an opt out system or any move towards a presumption in favour of donation would be incompatible with the beliefs of such groups or would risk donations being deemed authorised in situations where an individual was opposed for religious or cultural reasons.

12.8 Although some respondents were opposed to the principle of an opt out system on religious grounds (see also Chapter 3, paragraph 3.11), the most common view was that the right to opt out should meet the concerns raised. Respondents stressed the importance of promoting the right to opt out, and working with faith groups to ensure this message was effectively communicated.

12.9 It was also pointed out that there may be other people who were opposed to organ donation or an opt out system because of their personal moral, ethical or spiritual beliefs who may also be similarly affected by an opt out system.

12.10 One particular concern raised here was the need to respect the views of individual clinicians who may have religious or ethical objections to, or reservations about, an opt out system for organ donation.

12.11 Respondents also noted a range of other groups who, they suggested, needed additional protections because of their personal situations, and / or were less likely to be aware of an opt out system or less able to exercise their right to opt out. Additionally, some respondents argued that people in these already disadvantaged groups were more likely to become organ donors for the benefit of others. The groups highlighted included the following:

- Those with mental incapacity, cognitive impairment or mental ill health: Respondents were concerned that those unable to properly understand the implications of an opt out system – either on a temporary or long term basis – would be less able to express their wishes regarding organ donation.
- Those without immediate or close family: Respondents thought that those without immediate family would be less likely to have anybody who was both aware of their views on organ donation or their personal wishes regarding being a donor and able to represent those views in a situation where an individual was a potential donor and their views were not clear. It was suggested that this may affect those who were not in formal relationships, and those who were not close to – or were estranged from – their family.
- People living in care environments: Respondents thought that those living in care (either as children or adults with special needs) and without immediate family would also have less protection as the ‘state’ would be less likely to know the views of the individual and less motivated to protect their rights.
- Those with disabilities, or long term or life-limiting conditions: There were concerns that this group would be vulnerable if an opt out system led to a culture in which the healthcare system or individual clinicians prioritised the retrieval of organs over treatment.
- Hard to reach and socially disadvantaged groups: Respondents were concerned about a wide range of groups in society who might be less likely to know about or understand an opt out system and the right to opt out, and / or less likely or less able to exercise that right. They were, thus, more likely than other groups to become organ donors against their wishes. Such groups could include: those with sensory or communication impairments; the homeless; prisoners; young people / older people; recent immigrants; those with poor English; those with low reading / literacy skills; and those less likely to have internet access.

12.12 In addition, some queried whether there might be implications (either positive or negative) for LGBT people, and gay men in particular, given the current restrictions on ‘men who have sex with men’ donating blood. (It should be noted, however, that the deferral criteria covering blood and tissue donation are somewhat different from those for organ donors.)

Positive impacts and implications

12.13 Respondents who identified positive impacts and implications for particular equality groups focused on the following groups:

- Black and minority ethnic (BAME) groups: Respondents noted that organ donation rates were particularly low among BAME communities for a range of reasons (e.g. religious and cultural beliefs and practices, lower levels of awareness and understanding), while at the same time BAME people were over-represented on transplant waiting lists because of the prevalence of particular health conditions within certain communities. They thought that an opt out system had the potential to increase organ donation rates amongst BAME communities, and / or that an opt out system could increase the number of BAME people receiving transplants.

- People with disabilities / long-term health conditions: Respondents highlighted the fact that the need for a transplant was often linked to a disability or long-term health condition. Any increase in the availability of organs for transplant would, therefore, bring positive benefits for this group.

Views of those who did not think there were any equality impacts or implications

12.14 Those who did not think there were any equality impacts or implications offered three main views: they thought the system – in terms of both risks and benefits – would apply equally to all groups and that the right to opt out protected everyone including those in equality groups; they thought that the proposals outlined in the consultation paper adequately dealt with potential equality issues; or they thought that being a member of an equality group was not relevant to the issue of organ donation.

Other comments

12.15 A small number of other more general points were made with regard to equality implications and impacts. These included the following:

- That it would be important to maintain the confidence of equality groups through ongoing engagement and consultation during the policy development process, and to increase understanding of the views of different groups through further dialogue or research
- That any system would have to respond to potential equality impacts and implications and take account of the special needs of different equality groups (e.g. in the design of publicity and information campaigns; in producing information in different formats and different community languages; in offering simple and accessible ways to opt out)
- That clinicians and those involved in organ donation discussions with families should take account of the needs or views of different equality groups
- That the existence of equality concerns highlighted the more general concerns and risks associated with an opt out system for organ donation
- That any variability in the availability of SNODs or other specialist donation staff could mean that there were regional or service-based differences in the impacts or implications of an opt out system.

12.16 Finally, some respondents took the opportunity to reiterate more general points relating to the perceived risks and problems associated with an opt out system, or the potential benefits such a system might offer.

13. Other comments (Q15)

13.1 This chapter presents a summary of other comments made by respondents to the consultation. It presents an overview of comments provided at Question 15 which have not been covered in previous chapters, as well as other comments not relevant to any one individual question. It also draws together comments relating to a number of recurring themes identified across the consultation questions.

13.2 Question 15 asked for any other comments on what should be taken into account in relation to an opt out system:

Question 15: Do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?

13.3 In replying to Question 15, it was common for respondents to reiterate comments made at other questions, and to state or restate their overall views towards organ donation and transplantation and opt in and opt out donation systems.

13.4 The main themes in respondents' comments are summarised below. These often concentrated on the implementation of a soft opt out system, and the factors which respondents thought would be important to the successful introduction of such a system. The main points made included the following:

- **Information and publicity about an opt out system:** The introduction of any opt out system would need to be accompanied by sufficient general and targeted advertising and publicity and clear understandable information to ensure that everyone was aware of the change and its implications. This would help encourage conversations, change attitudes and create new norms. However, being able to reasonably assume that those who had not opted out had been aware of that option and had made a conscious decision not to do so would also be crucial to 'public and professional confidence' in the system, and to its ethical integrity. This would be important in avoiding the perception that organs are being taken without permission and ensuring that opting out or not is a properly informed decision.
- **Opting out:** The right to opt out would have to be promoted and respected, and the process for doing so would have to be simple and readily accessible. It would need to be easy for people to check their details and update them at any point.
- **Ethos:** Respondents stressed that patient welfare should be paramount, and that organ donation should be approached sensitively at all times.
- **Safeguards:** There would need to be thorough safeguards built into the system, which protected all individuals and took account of the needs of vulnerable groups, and the fact that people may change their minds. The need for an accurate and up-to-date central register of opt in / out wishes that was easily accessible to healthcare staff was highlighted. There would also be a need to maintain current practices with regard to (a) keeping the treatment of patients separate from the organ donation process in order to avoid blurring of roles, and (b) the requirement for sign off by two doctors after

cardiac death. There were also calls for effective monitoring arrangements to be put in place.

- **Moving towards an opt out system:** There was acceptance that the introduction of an opt out system would be controversial, and suggestions that it should proceed only if there is clear public support, and clear evidence of the benefits that might be achieved. It was common for respondents to recognise the complexity of the issue under discussion in their comments, and to acknowledge the need to balance pros and cons and to weigh up benefits and risks. Respondents also stressed the need for continued dialogue with stakeholder organisations and groups likely to be affected, including those opposed to, or with reservations about, a soft opt out system. It was also suggested that any legislation should include enabling provisions to take account of future developments in medical science / practice.
- **Implementation:** The system would have to be implemented as part of a package of measures including staffing, workforce-wide information, guidance and training, support for families, and public promotion, and this would need proper resourcing. Respondents also offered a range of specific suggestions regarding more operational aspects of an opt out system.
- **Cross-UK implications:** Any implementation of a soft opt out system in Scotland would have cross-border implications. Respondents highlighted the need for advertising on both sides of the border, and some suggested that potential organ or tissue recipients in Scotland should be given priority.
- **Promotion of organ donation:** Regardless of the donation system in place, respondents argued for increased advertising and promotion of organ donation. There needed to be a focus on positive stories of the benefits that transplantation can bring, and the difficulties faced by those in need of transplants. People should be encouraged to consider donation from the perspective of their own family.

13.5 In addition to the points above, personal stories from families of donors and those who had received donated organs were a common feature of the comments provided by individual respondents at Question 15 and elsewhere in the consultation. These stories were offered by those in favour of a soft opt out system as well as those opposed to it. Respondents were keen to highlight the positive aspects of having been involved in a decision to authorise a donation, and the very great benefits that could result from being a transplant recipient. And, while some valued the anonymity embodied in the current system, others said they would like to have the opportunity to get feedback about what had happened following a transplant.

Annex 1: Organisational respondents

NHS / local authority (14)

- Aberdeenshire Health and Social Care Partnership
- Glasgow City Health and Social Care Partnership
- South Lanarkshire Health and Social Care Partnership
- NHS Ayrshire and Arran Organ Donation Committee
- NHS Blood and Transplant
- NHS Fife
- NHS Forth Valley
- North Lanarkshire Council
- NHS Greater Glasgow and Clyde Organ Donation Committee
- NHS Highland Organ Donation Committee
- NHS Lanarkshire
- NHS Lothian Organ Donation Committee
- Scottish National Blood Transfusion Service
- Western General Hospital Edinburgh, Clinical Lead for Organ Donation and Specialist Nurses in Organ Donation

Professional organisations / regulatory bodies (12)

- British Medical Association
- British Transplantation Society
- Faculty of Advocates
- Faculty of Intensive Care Medicine
- General Medical Council
- Human Tissue Authority
- Law Society of Scotland
- Royal College of Nursing
- Royal College of Physicians of Edinburgh
- Scottish Council on Human Bioethics
- Royal College of Physicians and Surgeons Glasgow
- Scottish Intensive Care Society

Charities, voluntary sector organisations and patients' groups (11)

- British Heart Foundation Scotland
- British Kidney Patient Association
- Children's Liver Disease Foundation
- Cystic Fibrosis Scotland
- Kidney Research UK
- Liver Transplant Support UK
- National Kidney Federation (NKF)
- Return to Life
- Revival
- Together (Scottish Alliance for Children's Rights)
- Transplant Kids

Faith groups (8)

- CARE for Scotland
- Catholic Parliamentary Office
- Christian Medical Fellowship (CMF)
- Church in Society Committee of the Scottish Episcopal Church
- Church of Scotland Church and Society Council
- Ekklesia
- Muslim Council of Scotland
- Scottish Council of Jewish Communities

Annex 2: Question response rates

Table A2.1: Number of comments made at each question and response rate

Question	Number of responses	Response rate (% of total 824)
Question 1: What do you think of the principle of a soft opt out system for Scotland? [I support the principle of a soft opt out system in Scotland / I do not support the principle of soft opt out]	801	97%
Question 2: Are there any changes you would make to the current opt in authorisation system, other than moving to an opt out system?	455	55%
Question 3: Where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor's family opposes the donation? [Medical staff should still proceed with the donation / Medical staff should not proceed with the donation]	800	97%
Question 4: If there was a soft opt out system, what do you think of the proposed checks above? [These are sufficient to decide if a donation can be deemed to be authorised / These are not sufficient to decide if a donation can be deemed to be authorised / Don't know]	798	97%
Question 4(a): If you think these are not sufficient, what other checks would be needed (apart from those covered in Questions 6 to 8 below)?	98	12%
Question 5: In any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family? [The donation should still proceed / The donation should not proceed / Don't know]	805	98%
Question 6: If there was a soft opt out system, what do you think about the categories of people (described in the consultation paper, pages 15 to 17) for whom explicit authorisation would still be needed from the person themselves or a family member? [The categories are sufficient / The categories are not sufficient / Don't know]	797	97%
Question 6a: If these are not sufficient why do you think this?	125	15%
Question 7: In what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?	610	74%
Question 8: Under what age do you think children should only be donors with explicit authorisation? [Under 12 / Under 16 / Under 18 / Other, please specify]	795	96%
Question 9: For children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available? [They should be allowed to authorise donation of a child's organs or tissue in those circumstances / They should not be allowed to authorise donation of a	804	98%

child's organs or tissue / Don't know]		
Question 10: In any opt out system, what provisions do you think should apply to the less common types of organs and tissue? [Deemed authorisation provisions should apply to all organs and tissue / Deemed authorisation provisions should only apply to the more common organs and tissue]	774	94%
Question 11: Which tests do you think medical staff should be able to carry out on a potential donor before they withdraw life-sustaining treatment? Blood tests? Urine tests? X-rays? Tests on a sample of chest secretions? Tests on the heart? [Yes / No / Don't know]	789 – 795	96%
Question 12: If you answered no to some or all options in Question 11, are there any circumstances when particular tests could be permitted? [If the person had previously made clear they wished to be a donor / If the donor's family provided consent on the donor's behalf / Such tests should never be permitted before death]	66	8%
Question 13: Where it is agreed a patient's condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given?	798	97%
Question 14: What do you think about allowing people to appoint one or more authorised representatives to make decisions for them? [This should be allowed / This is not necessary / Don't know]	804	98%
Question 14a: If you think this should be allowed, in what circumstances do you think an authorised representative would be useful?	305	37%
Question 15: Do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?	342*	42%
Question 16: What do you think about providing Chief Medical Officer (CMO) guidance to encourage clinicians to refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor? [CMO guidance should be provided to encourage more referrals / CMO guidance should not be provided / Other]	792	96%
Question 17: What do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible? [This should be a requirement / This should not be a requirement]	797	97%
Question 18: Do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? [Yes / No / Don't know] If yes, please provide details.	791	96%

* Note that the 342 Question 15 responses include (i) responses incorporating comments directly related to tick-box questions which did not provide a space for additional comment; and (ii) 100 responses comprising the words 'no', 'none', etc.



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