Department of
Health
An Roinn Sláinte
Männystrie O Poustie
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Summary of responses to the public consultation: *Introduction of a statutory opt-out system for organ donation for Northern Ireland*

September 2021

CONTENTS

List of abbreviations

ACRONYM	**EXPANSION**
BHF	British Heart Foundation
CAG	Clinical Advisory Group
DoH	Department of Health
HSC	Health and Social Care
HSCB	Health and Social Care Board
HTA	Human Tissue Act
MLA's	Member of the Legislative Assembly
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NI	Northern Ireland
ODR	Organ Donor Register
PHA	Public Health Agency
SNOD/SN-OD	Specialist Nurse - Organ Donation

INTRODUCTION

1. On 22 July 2020, the Health Minister, Robin Swann MLA, announced his intention to consult the public on proposals from 11 December 2020 to 19 February 2021, to engage with patients, clinicians, stakeholders and the general public on proposals to change the current system of consent for organ donation in Northern Ireland (NI).

2. Consultation enables an assessment to be made of the views of those who are affected by policy decisions or changes to services. It can help policy-makers to become aware of issues and problems that the proposed changes may pose for various groups that they might not otherwise discover.

3. Therefore, the Department of Health in Northern Ireland, referred to in this document as “the Department” or “DoH”, ran a consultation from 11 December 2020 to 19 February 2021 to engage with patients, clinicians, stakeholders and the general public on proposals on how such a system could be introduced through a change to the current legislation on organ donation.

4. This report explains the approach to the public consultation and provides a summary of the views raised through both written consultation and a series of virtual public engagement sessions. It concludes with the Department’s response to those issues.

5. The objective of the proposed change is to increase the current rate of consent for organ donation to proceed after a person’s death. Achieving this will increase the overall number of donors, and ultimately the number of lifesaving organs available for transplantation.

Background

6. Organ and Tissue donation saves and improves many lives each year and one donor has the potential to save 9 lives. Last year in NI there were 51 deceased donors, resulting in 113 transplants throughout the UK. In total, 87 NI residents received transplants.

7. NI, along with England, Scotland and Wales, is part of an equitable UK organ sharing scheme. This means that NI citizens benefit from being part of the UK 'pool', in which organs from deceased donors anywhere in the UK are transplanted into individuals with the greatest need and the best chance of success. The system, including the NHS Organ Donor Register (ODR), is operated by NHS Blood and Transplant (NHSBT) on behalf of all regions of the UK.

8. As part of this system, NI patients who need a heart, lung, liver, pancreas, or small bowel transplant can travel to specialist hospitals in the UK to have their operations and the same is true for some tissue transplants. The specialty of renal surgery and transplantation means kidney transplants, from both living and deceased kidney donors are normally provided for NI patients at Belfast City Hospital.

The Current 'Opt-In' System

9. Currently in NI there is an 'opt-in' framework for consent for organ donation to proceed after a person's death. This means that donation will only ever proceed if a person had given their express consent for organ donation, usually by signing on to the ODR and/or the person's family supports the donation proceeding. In the absence of a decision being recorded on the ODR, or the family are unaware of their loved one's donation intentions, they are asked to decide on their behalf.

10. Only a small proportion of people (around 1%) die in circumstances where it may be possible for their organs to be donated. Usually this will be in a hospital intensive care setting, and in these circumstances, families are given the option of consenting to organ donation on behalf of their loved one. They are usually referred to a Specialist Nurse - Organ Donation (SNOD) working within the intensive care unit and equipped with the specialist knowledge and skills to discuss organ donation and, if known, their loved one's intentions or decisions.

11. Whilst surveys regularly show that over 80% of the population supports organ donation, only 49% have recorded this decision on the ODR. Although this figure has been increasing steadily from 30% since 2013 through local and national awareness-raising campaigns, the ODR is not yet truly representative of the NI population's willingness to donate their organs and tissue after their death, as 51% of people have not formally recorded a decision.

Why Move to An Opt-Out System?

12. A number of other countries have adopted an ‘opt-out’ system of consent as a means of increasing the number of organs available for transplantation, and better reflecting the levels of public support for organ donation. Instead of requesting that everyone who supports organ donation should ‘opt in’ and record their decision on the ODR, it is considered that everyone – with the exception of certain exempt groups – would be willing to donate their organs unless they have formally opted out on the ODR, or expressed an objection to a close friend or relative during their lifetime that they do not want to be a donor after their death. This is sometimes referred to as ‘deemed consent’.

13. Since 2015, when Wales introduced a statutory opt-out system for organ donation, all residents of the UK have been able to record a decision not to be an organ donor. In NI, approximately 2000 people (0.1% of the population) have used the ODR to formally record a decision not to donate.

Improving the Consent Rate for Organ Donation in Northern Ireland

14. The ‘consent rate’ is an internationally used measure to indicate the number of potential donors for whom consent to proceed with donation is confirmed after death. It is measured by the number of families who agree to support donation going ahead divided by of the number of potential donor families approached for donation. The consent rate is always higher in cases where families already know their loved one’s intentions.

15. The international standard for world class performance is recognised to be an 80% consent rate. This is the target consent rate to which all UK regions have aspired since the previous UK-wide strategy (2013-2020), was introduced and remains the aspiration. The consent rate in NI has remained at around two thirds of potential cases and has not increased significantly for several years despite consistently high levels of support for organ donation and consistent growth in registrations on the ODR.

16. This means that each year, between three and four out of ten families in NI, when faced with the decision, did not give their consent for donation to proceed,

sometimes against the known intentions of their loved one. Understanding and addressing the reasons for their refusal in these difficult circumstances is key to improving the consent rate.

Comparing Consent Rates across the UK

17. Consent rates for the year 1 April 2019 - 31 March 2020 in each region of the UK are summarised in the table below:

Nation	Deceased Organ Donors (per million population)	Consent Rate (%)
England	23.5	68.3
Northern Ireland	**26.1**	**64**
Scotland	18.4	64.8
Wales	27.1	70.7

18. NI saw an increase in the consent rate in 2020/21 to 79%. However, due to Covid-19 and other factors this is not considered a sustained increase to the overall number of consented donors and organs donated, was significantly lower than previous years.

19. Since the introduction of the opt-out system in Wales in 2015 and the corresponding information campaigns, there has been an increase in both consent rate and donation rate. The consent rate increased from 58% in 2015 to 70.7% in 2020, although the impact was not immediate and took several years to take effect, following an extensive media promotion and information campaign by the Welsh government.

20. In England, a new opt-out system came into effect from 20 May 2020, however it is too soon to analyse any impact on consent rates. Scotland's opt-out system came into effect from 26 March 2021.

21. In NI, it is proposed that the introduction of opt-out legislation could contribute towards an increase in the consent rate over time, similar to Wales, which will mean:

- If you want to be a donor, you can still register to be a donor (opt in) on the NHS ODR and inform those close to you of the decision;

- If you don’t record a decision to be a donor or let those close to you know your donation decision, you will be considered as having no objection to becoming a donor (i.e. ‘deemed consent’);
- If you do not want to be a donor, you must either register not to be a donor (opt out) on the ODR, or otherwise make your decision known to those close to you; and
- You can also nominate a representative to make the decision for you after your death.

22. It is important to note that the proposed move to an opt-out system for NI would not change the fact that individuals remain responsible for decisions about what happens to their organs after they die.

Promoting Organ Donation in Northern Ireland

23. It is acknowledged that legislative change alone will not achieve an organ donation consent rate of 80% or above. Rather, it is seen as a potential enabler of further progress towards this target, if combined with increased public awareness. Countries with mature opt-out systems and high rates of consent, e.g. Spain, tend to also have high levels of public support and understanding around the benefits of organ donation and transplantation. Any move to an opt-out system for NI must therefore be combined with appropriate public education and communication for the maximum benefit to be realised.

24. The DoH in NI already has a statutory duty to promote organ donation, and in 2018 published a policy statement outlining its key commitments to deliver this. The overall objective of the policy is, and remains, to promote a positive, cultural, long term change in attitudes and behaviours in relation to organ donation. The Department is working with the Health and Social Care (HSC) system, the public sector (including local government and the education system), and wider society, to promote organ donation through a coordinated and sustained programme of communication. These commitments are not impacted by the proposed move to a statutory opt-out system, and will remain in place during and after implementation of any new system.

Consultation

25. The public consultation was announced by the Minister of Health, Robin Swann MLA on 11 December 2020. The consultation ran for a period of 10 weeks from 11 December 2020 to 19 February 2021.

26. The Organ Donation Bill Team from the DoH with input from the Organ Donation Steering Group developed the consultation document. The Steering Group comprised HSC clinicians from the renal transplant service and intensive care, as well as representation from NHS Blood and Transplant (NHSBT), Public Health Agency (PHA), Health and Social Care Board (HSCB) and the Department.

27. The consultation sought the public's view on how to introduce an 'opt-out' framework for consent for organ donation in NI, including the following:
    - Their current intentions or decisions about donating their organ/tissue after they die;
    - Whether they have shared this decision with their loved ones;
    - Whether a move to a statutory opt-out system would change their decision;
    - The groups of people who should be exempt from the proposed changes;
    - The role that their family and loved ones should play;
    - The scenarios in which deemed consent should not be applied, e.g. donation for research purposes, or for novel and rare types of transplants; and
    - How we should engage with the public to raise awareness of the proposed changes in the law, and the focus for future communications.

28. The public was able to submit views in the following ways:
    - Submit their responses using an online questionnaire;
    - Downloading the form and emailing to the Department at: organdonation@health-ni.gov.uk; and
    - Download, print and post the form to Organ Donation Consultation, Department of Health Castle Buildings.

29. The Department was also able to provide the document in alternative formats upon request.

Engagement Plan

30. To ensure that the consultation engaged as widely as possible with the general population of NI, the clinical community, and government, an engagement plan for these audiences was required. Garnering maximum engagement and feedback will ensure a fit for purpose system is developed and will facilitate maximum buy-in and support for the soft opt-out system.

31. The Engagement Plan's aim was to maximise general community engagement for the consultation. The main elements of the community engagement plan can be summarised into three main components consultation launch, consultation engagement activities and awareness activities. A copy of the Engagement Plan is attached at **Annex A.**

32. The engagement sessions took place within the initial weeks following the launch when it was fresh in people's minds and they will generally reply promptly. Other activities consisted of regular reminders and ongoing engagement sessions. Regular reminders were issued using email and social media.

33. Given the new context of operating within COVID-19 restrictions, the public consultation engagement sessions were all held virtually. With this in mind, consideration was given to the most appropriate tool for each audience, with Zoom being the preferred platform.

1. WRITTEN CONSULTATION RESPONSES

The Department received 1917 written responses, with 1899 using the online pro forma questionnaire provided and the remaining 17 providing more general comments. Not all respondents responded to every question.

The breakdown of consultation responses is as follows:

	Category	Number of responses
1	Members of the public	1771
2	HSC professional individuals	108
3	Health professional groups/organisations	15
4	Voluntary sector organisations	12
5	Public sector organisations	4
6	Religious organisations	3
7	Political organisations	3

A list of organisations which submitted a response is provided at **Annex B**.

A summary of the Departments analysis of the responses to the 15 consultation questions is provided in the section below. With a sample of the comments received is included at **Annex C**

Consultation Questions

Your Organ Donation Decision

Q1. Would you be willing to donate your organs and/or tissue after your death?

There were 1885 responses to this part of the question.

Option	**Total**	**Percent**
Yes – all organs and tissue	1595	83.20%
Partly - Some organs / tissue	179	9.34%
No – I would not like to donate any organs or tissue	57	2.97%
Not made a decision	54	2.82%
Not Answered	32	1.67%

- Over 92% of respondents are willing to donate either all or some of their organs or tissue.
- The majority of the comments received show strong support for the system and emphasised both the importance and the benefits of the new system.

- Of 3% who would not be willing to donate organs or tissue raised issues around the government taking a personal decision out of their hands while others commented that organ donation went against their beliefs.
- For those undecided most felt that they needed more time and/or information to make a more informed decision around organ donation.

Q2. Have you already recorded your donation decision, e.g. by joining the NHS Organ Donor Register or otherwise?

There were 1878 responses to this part of the question.

Option	**Total**	**Percent**
Yes	1504	78.46%
No	226	11.79%
Don't know	148	7.72%
Not Answered	39	2.03%

- Almost 80% of respondents advised that they had already recorded their donation decision.
- The majority of comments received in relation to his question were very similar to those in Question 1 above.

Q3. If you answered ‘yes’ to the above, have you shared your decision with your loved ones?

There were 1722 responses to this part of the question.

Option	**Total**	**Percent**
Face to face conversation	1571	81.95%
Social media platform (e.g. WhatsApp, Facebook)	285	14.87%
In written form (text, email, as part of a Will)	103	5.37%
Other - Please specify	27	1.41%
I have not shared my decision	126	6.57%
Not Answered	195	10.17%

- The most common way in which people have shared their decision is through face to face conversations.
- Social Media and in written form were the next most popular ways in which people had shared the decision.
- There were 31 responses that they had used other methods to share their decision these included have it on their drivers licence and carrying a donor card.

- It is also worth noting that 126 respondents who had indicated that they were organ donors have not shared that decision.

Q4. Would a move to a statutory opt-out system change your decision regarding organ donation?

There were 1881 responses to this part of the question.

Option	Total	Percent
No - It would make no difference	1359	70.89%
Yes - It would make me want to become an organ donor after my death.	477	24.88%
Yes - It would make me no longer want to become an organ donor after my death.	45	2.35%
Not Answered	36	1.88%

- A large majority of the respondents indicated that the change of system would have no impact on their decision to donate which suggests that these people are around organ donors.
- Almost 25% respondents indicated that the introduction of the new system would make them more likely to become organ donors with some indicting that it would now be easier to become organ donors.
- Those that indicated that they would no longer want to be donor indicted that this was due to them not being able to make the decision for themselves.

<u>Exemptions to Opt-Out Legislation</u>

Q5: To what extent do you agree that opt-out legislation should NOT apply to children (those under 18 years) and that the donation decision should be made by those with parental responsibility?

There were 1896 responses to this part of the question.

Option	Total	Percent
Strongly Agree	425	22.17%
Agree	491	25.61%
Neither agree or disagree	269	14.03%
Disagree	381	19.87%
Strongly disagree	330	17.21%
Not Answered	21	1.10%

- The results of this question were quite evenly spread with 47% in agreement that children should be exempt while 37% didn't agree with 14% not committing one way or the other.

- For those that didn't agree the most common theme was that children have the capacity to give consent from 16. This was highlighted by a comment which advised that the NI the courts have stated that under-16s will be competent to give valid consent to a particular intervention if they have 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed' (known as 'Gillick competence').

Q6: Do you think that any of the following people should be exempt from deemed consent for organ donation and the family should provide that consent?

There were 1350 responses to this part of the question.

Option	Total	Percent
Adults who lack capacity	971	50.65%
Visitors, including cross-border workers from ROI & tourists to Northern Ireland	689	35.94%
People who are temporarily resident in Northern Ireland (e.g. students from overseas or RoI, overseas Armed Forces personnel), people on work placements from overseas or RoI	651	33.96%
Prisoners	164	8.56%
People whose identity is unknown	604	31.51%
Others - Please specify	67	3.50%
Not Answered	567	29.58%

Other

There were 75 responses to this part of the question.

- Over half of respondents agreed that adults that lack capacity should be exempt from deemed consent.
- Views include those adults with advanced dementia or severe learning difficulties who are unlikely to be able to understand the consequences of not opting out; and that support is provided to help someone to make an informed decision where possible and appropriate.

- That said respondents also felt that consideration should be given as to whether the person expressed their wishes at a time before capacity to consent was lost.
- There was reasonable support for exemptions to apply to Visitors, including cross-border workers, people temporarily resident in Northern Ireland and also Peoples whose identity was unknown.
- There was less support for the exemption of prisoners.
- The majority of the comments received in respect of 'Others' relate to the lowering the age of deemed consent. While a number of ages were represented the most of comments expressed a desire that the age of deemed consent should be 16.
- There were no new groups mentioned that should have be considered for exempt from deemed consent.

The Role of the Family and Loved Ones

Q7: To what extent do you agree that, in situations where there is a known decision to donate recorded on the NHS Organ Donor Register, the family should always be asked about the last known organ donation decision of their loved one, to ensure it's still accurate?

There were 1900 responses to this part of the question.

Option	Total	Percent
Strongly Agree	333	17.37%
Agree	434	22.64%
Neither agree or disagree	222	11.58%
Disagree	507	26.45%
Strongly disagree	404	21.07%
Not Answered	17	0.89%

- Just over 40% agreed that should always be asked about the last known organ donation decision were almost 48% disagreed.
- A large number of respondents thought that it was important that families of next of kin had an important consultative role to play at the point of organ retrieval.

- There was significant number of respondents said that an express decision on organ donation should always be respected and that members of the deceased family should not able to override the deceased known decision.
- Others felt that family should be consulted to ascertain if they had known decision with regards organ donation when that that deceased had not been recorded on the Organ Donation Register or elsewhere.
- Two respondents considered that families should not play any part in the process.
- Other respondents thought that it was vital that the Department undertake a fully funded education and awareness campaign to ensure that people share their donation decision with their family and loved ones.

Q8: To what extent do you agree that, in situations where there is no known organ donation decision, the family should always be asked about whether their loved one would have objected to organ donation?

There were 1897 responses to this part of the question.

Option	Total	Percent
Strongly Agree	520	27.13%
Agree	662	34.53%
Neither agree or disagree	227	11.84%
Disagree	310	16.17%
Strongly disagree	178	9.29%
Not Answered	20	1.04%

- The majority of respondents (62%) agreed that in situation where there is no known organ donation decision, the family should always be consulted.
- Respondents indicated in their comments that families should only have to decide on organ donation where an individual's decision is not known.
- There was also concern around this discussion would be handled in what is a very traumatic time for family and friends. Highlighting the importance of people sharing their decision around organ donation.
- Some respondents felt that the introduction of an opt-out system would take the responsibility of making the decision away from the grieving relatives.

Q9. Which of the following statements best summarises how the introduction of opt-out legislation would influence your support for donation of a loved one's organs and/ or tissues?

There were 1885 responses to this part of the question.

Option	Total	Percent
I currently support organ donation and would continue to do so.	1706	89.99%
I currently do not support organ donation and would continue to not support	26	1.36%
It would make me more likely to support organ donation	83	4.33%
It would make me less likely to support organ donation	70	3.65%
Not Answered	32	1.67%

- It is clear from the responses to this question that the majority of people support organ donation and would continue to do so with the introduction of opt out legislation.
- 4.33% of respondents also stated that the introduction of opt out legislation would make it more likely for them to support organ donation.
- Alternatively, 3.65% stated it would make them less likely to support organ donation.
- A relatively low number of respondents (1.36%) do not support organ donation and would continue to do so.

Novel and Rare Transplants

Q10. To what extent do you agree that organs and tissues that could be used for rare or novel types of transplantation (e.g. limb or face) should be excluded from opt-out legislation?

There were 1889 responses to this part of the question.

Option	Total	Percent
Strongly Agree	279	14.55%
Agree	419	21.86%
Neither agree or disagree	430	22.43%
Disagree	425	22.17%
Strongly disagree	336	17.53%
Not Answered	28	1.46%

- The general consensus from the comments received for this question was that Novel and Rare transplants should be kept separate from the other more common types of transplant that are currently taking place.
- There were no comments received which thought that these types of transplants should be included in the new system.
- One respondent felt that it was important to revisit this area in the future as these types of transplants considered to be novel and rare today may become more mainstream overtime
- One respondent thought that face and limb transplants should never be allowed.

Research

Q11. To what extent do you agree that the donation of organs and tissues for research purposes should be excluded from statutory opt-out and the family approached for express consent?

There were 1891 responses to this part of the question.

Option	**Total**	**Percent**
Strongly Agree	438	22.85%
Agree	570	29.73%
Neither agree or disagree	315	16.43%
Disagree	356	18.57%
Strongly disagree	212	11.06%
Not Answered	26	1.36%

- The overall consensus is that organ donation for research purposes should be excluded from the new system and should require either express consent or remain as an opt-in option before being undertaken
- Other points raised included:
    - We need to be mindful that past revelations around harvesting of organs could be attributed to the responses to this particular question;
    - Extending the opt-out system to include donation for research may lead some people to opt out who would be happy to donate for transplantation alone; and
    - Most people will be aware of organ donation, have given some thought to their own wishes, and many people will have discussed their wishes with their family; again, the same is not true of participation in research.

Faith and Beliefs

Q12. To what extent do you agree that people’s faith or beliefs should continue to be taken into consideration as part of the donation discussion after any move to an opt-out system?

There were 1893 responses to this part of the question.

Option	Total	Percent
Strongly Agree	398	20.76%
Agree	616	32.13%
Neither agree or disagree	302	15.75%
Disagree	320	16.69%
Strongly disagree	257	13.41%
Not Answered	24	1.25%

- Most respondents felt that it was important that peoples religious, personal beliefs and values need to be considered in the organ donation process but that the proposed new system still gave them the option to opt out of organ donation.
- A number of respondents also felt that while the religious beliefs of the next of kin should be considered it should not override the decision be the deceased if it is known that they wished to be considered for organ donation.
- One respondent thought that the move to opt-out system ran the risk of people's genuine conscientious objections being ignored.
- Other respondents also felt it was important that new system be effectively communicated to all religious and faith groups within NI and would be important that the Department worked alongside the faith leaders to ensure the message was communicated effectively.
- One respondent also raised concerns that an opt-out system would increase the risk that people’s conscientious objections are ignored.
- Another respondent believed that religion should have no bearing on the process.

Raising Awareness of the Change in Legislation

Q13. What do you think is the most important and effective activity for raising awareness of the law change?

There were 1887 responses to this part of the question.

Option	Total	Percent
TV, radio	1556	81.17%
Social media adverts	1538	80.23%
Out of home advertising (e.g. posters on public transport, bill boards etc)	690	35.99%
Adverts in print media (e.g. newspapers, magazines etc)	355	18.52%
Mail drop to all houses in NI	882	46.01%
GP surgeries	618	32.24%
Places of worship	226	11.79%
Local councils	281	14.66%
School/Curriculum resource	860	44.86%
Other – please specify	31	1.62%
Not Answered	30	1.56%

- General consensus was that it was vital that there was widespread advertisement and education programme in place before the new system was implemented.
- The vast majority of respondents considered that TV and Radio and social media adverts would be most important and effective activity for raining awareness.
- Other areas that received strong support was Mail drops, out of home advertising and schools.
- Some of the ideas suggested under other included:
  - Sporting organisations
  - Community Groups
  - Schools and Universities
  - All Health care settings
  - Work settings e.g. Civil Service
  - Use of previous organ donors and their families
- Respondents also felt that any changes in the law in NI must be done in parallel with a public information campaign in order to educate, inform and raise awareness of upcoming changes to the law.

- It was also suggested that people who had received organs and their family should be involved in raising the awareness of the new system and organ donation on general.

Q14. If you have any other comments or views you would like to express in relation to the proposed opt-out legislation?

Approximately 450 people responded to this question. Our analysis did not uncover any new issues that had not already been covered in previous questions.

Respondents frequently used this question to either set out support for the new arrangements, sometimes detailing their personal experience of organ donation (either directly as a transplant recipient or member of a donor family, or as a medical professional, or to set out their concerns about the new approach.

Q15. If you have comments or views you would like to express in relation to the Equality Screening, Disability Duties and Human Rights Assessment Template or Rural Screening Document that accompany this consultation document?

There was a total of 30 comments received in respect of this question. All of the comments received related to concerns around the Human Rights Assessment.

The most notable themes relate to fears around medical mistrust with opt-out viewed as dictatorial and a method of increasing Government control of organs.

For those opposed to the change, registering an active decision to not donate protects their freedom of choice.

2. PUBLIC CONSULTATION MEETINGS

Seven virtual public engagement sessions were facilitated by the Department with a further session, for MLA’s, being facilitated by the British Heart Foundation (BHF). Attendees included members of the public, transplant recipients and relatives of organ donors, voluntary and community organisations, elected representatives, and HSC employees. The number of attendees were as follows:

Date	Meeting place	Attendees
12 January 2021	Public Engagement Session (1)	4
13 January 2021	Public Engagement Session (2)	9
15 January 2021	Young People Engagement Session	20
19 January 2021	Public Engagement Session (3)	15
20 January 2021	Public Engagement Session (4)	15
21 January 2021	AGENI Engagement Session	4
26 January 2021	U3A Engagement Session	10
28 January 2021	BHF Engagement Session	22
	Total Attendees	99

3. FORMAT OF MEETINGS

Organ donation facts and information, as contained in the consultation document, were presented at each meeting via a slide presentation. This included an explanation on what would change once the opt-out system was implemented, relevant statistics about ODR registration and transplant waiting lists at a local level and how the opt-out system had impacted donor levels in England and Wales who have already adopted an opt-out system.

This was followed by Question and Answer session on the proposed new system, during which attendees could ask questions of HSC clinicians, NHSBT SNOD’s and the Department. The Session also included a number of short polls which provided feedback on various aspects of the sessions.

Attendees also viewed a series of short films produced by the Northern HSC Trust’s Organ Donation Committee, portraying the stories of local people who have either received an organ transplant, or consented to the donation of organs on behalf of a deceased relative.

In the main, participants at the engagement sessions were supportive of the proposals and provided useful feedback. A summary of the key questions and comments addressed during the session are as follows:

- Does the body have to be taken immediately like organ donation or can close family ones have time to “see” the physical body before the body is removed? It probably is quite important emotionally and psychologically for the grieving family?

- What measures have been put in place to ensure the resource is available (additional trained medical staff) to meet the increase in available organs if this legislation is implemented?
- Given that opt-in relies on family consent and opt-out also relies on family consent, how would you best describe the change in practice/outcomes that the change in legislation would bring about? A soundbite/elevator pitch that would work in the media context or as an explanation to a friend.
- What does it mean to NHSBT that NI would become the 'final piece in the jigsaw' across the United Kingdom? How does the whole of the UK being Opt-Out mean to us all as a whole?
- Why not stop Next of kin being able to override a person's wishes who has consciously chosen to donate. With opt out, not everyone can make clear their wish to opt out and given it's done online, data privacy is also an issue, especially as it might affect potential treatment, just like racial bias in medicine
- As far as I know there are many 17-year olds who sign the ODR when they receive their diving test form. These would be exempt from the new Opt-Out System. How can you raise the profile for people under 18 to register their wishes?

Organ Donation Clinical Advisory Group

As part of the engagement process Department established an Organ Donation Clinical Advisory Group (ODCAG), which provides a mechanism for clinicians and other stakeholders with relevant expertise to advise the Department on the development and implementation of the legislation to introduce a statutory soft opt out-system for organ and tissue donation in NI.

Members of the group include NI clinical leads for Organ Donation, Organ Utilisation and Specialist Nursing, as well as representatives from NHS Blood and Transplant, the Public Health Agency, the Human Tissue Authority, and the British Medical Association.

At its initial meeting on 27 April 2021, the ODCAG suggested that the draft Bill should place a statutory duty on my Department in respect of promoting ongoing awareness of the new opt-out framework, and of reporting regularly to the Assembly on its impact and effectiveness. The consultation showed strong support for the need for an information campaign around the law change. The ODCAG's proposal would achieve this in a way which ensures that both present and future generations would continue to be fully informed about the legislative framework, and would therefore be able to make fully informed decisions about whether or not they wish to become organ donors.

Statutory provision of this kind would mitigate any concerns about a potential lack of awareness or informed choice regarding deemed consent, both now and in the future. This could be provided for in the draft Bill through a consequential amendment to Part 4 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016, effectively to enhance my Department's existing statutory duties which it executes through a comprehensive promotion and communications programme.

4. DEPARTMENTAL RESPONSE

The Department would like to thank all organisations and individuals who participated in the public consultation. We highly value the time taken to contribute your views.

The consultation asked 15 questions, covering areas such as your organ donation decision, exemptions to opt-out, role of the family and loved ones, novel and rare transplants, research, faith and beliefs and raising awareness of the change in legislation.

The responses provided invaluable insight into the views of members of the public and organisations regarding the proposals. The responses were analysed in detail by the Organ Donation Bill Team in the DoH.

The vast majority of respondents to the consultation expressed broad support for the introduction of a statutory opt-out system for organ donation in NI. As reflected in the summary of responses illustrated above, and the sample of comments at **Annex C**, a range of views, concerns and requests for clarification have been submitted and these will be addressed in this response.

However, no issues have been raised which will cause us to deviate from the policy intention as outlined in the public consultation and it is the Departments intention to move forward and to seek Executive approval to introduce legislation for a statutory opt-out system for organ donation in NI.

Therefore, the final policy position for the Bill is as follows:

- It will be considered that everyone living in NI agrees to donate their organs when they die, unless they have confirmed otherwise by opting out on the ODR, or otherwise making their decision known, or they are from one of the excluded groups;
- Individuals will still have the choice about whether or not they want to become a donor;
- Families will continue to play an important role in the consent process in all cases, however the nature of the family discussion would change compared to the present system (this is known as **soft opt-out**) – the family will always be asked about the last known organ donation decision of their loved one, to ensure it is still accurate;
- Decisions based on faith and belief will continue to be respected;
- Deemed consent should **not** be applied in the case of donation of organs for research purposes, for which there is a separate process covered by the Human Tissue Act;
- Deemed consent should **not** be applied in the case of novel and rare types of transplants (e.g. face, limb, genitals). Learning from the experience of other jurisdictions in this regard, rather than prescribing lists of exempt organs, NI Regulations will explicitly state the organs to which deemed consent will apply (i.e. heart, lungs, liver, kidneys, pancreas and small bowel, as well as tissue including heart valves, corneas and bone).
- The Department’s existing statutory duty to promote and report on organ transplantation will be extended to include specific advice and information within the annual campaign and report about the law on statutory soft opt-out and about how people can record their decisions if they wish.

This section sets out the Department's response to the views submitted in relation to each section of the consultation.

Your Organ Donation Decision

The consultation highlighted that the vast majority of the respondents (92%) were willing to donate either all or some of their organs or tissues.

Therefore, the Department in implementing this new system for Organ Donation we want everyone to consider what the new policy means for them, discuss organ and tissue donation with their friends and family and decide whether they wish to be a donor, and then record their decision. This will be important as when the new legislation comes into effect if someone has not recorded a decision on the Register to say that they do not wish to donate their organs, unless they are excluded, they will be considered as having no objection to organ donation. However, if organ donation is a possibility on someone's death, there will always be a personal conversation with the family to understand what their loved one's wishes were.

It is crucial that everyone takes a decision on organ donation - whether that is to donate or to not donate - registers their decision on the Register and makes their decision known to their family and friends. In this way, families can be certain that they are acting according to their loved one's wishes.

Exemptions of Opt-out Legislation

The Department believes that certain exceptions should be made to the general rule that everyone will be considered willing to donate their organs after their death unless they have recorded a decision to not donate. This believe was in line with the majority of respondents to the consultation.

People who lack mental capacity, children under 18, people not ordinarily resident in NI, including visitors, those temporarily resident in NI and prisoners, before their death, are less likely to be aware of the system, understand the changes and make an informed decision. As such, these groups will be excluded from the new arrangements. Building on how the system works in England and Wales, the Code of Practice which will be developed by the HTA will set out how the new arrangements will work in practice, including the discussions between the specialist nurses and the family, to establish how long someone has been ordinarily resident in NI.

Children Under 18 Years Old

As mentioned in chapter 2, 53% of those who responded to the question about who should be excluded from the new arrangements supported excluding children below 18. There were exceptions to this, with some suggesting that the cut-off point should be at different ages, ranging from 16, to over 18.

The Department agrees that the new arrangements may be too complex for children below 18 to understand and decide what action they need to take, and for this reason children below 18 will not be part of the new arrangements. This means that unlike adults, for children below 18, there will not be a presumption in favour of organ donation if they have not opted out. Indeed, the age of 18 is widely recognised as the age at which one becomes an adult, and gains full citizenship rights.

People Who Lack Capacity

The consultation identified a strong sentiment that people who do not have the mental capacity to understand the changes and take the relevant action should be excluded. The Department agrees with this position. Currently, any person can record a wish to donate their organs without their mental capacity being assessed. This will not change, but those who lack the capacity to understand the effect of the new arrangements will not have their consent 'deemed' on their death, if they have not recorded an express decision.

People Who Are Not Normally Resident in NI

We also agree with the view that people who had not been ordinarily resident in NI (for example tourists, students, cross-border workers and prisoners) should be excluded from the new arrangements. This is because they are less likely to be aware of the changes, understand how they impact on them and the action they need to take.

The Role of the Family and Loved Ones

It was clear from the responses received that the majority of people (89%) support organ donation and would continue to do so with the introduction of opt-out legislation.

A significant number of respondents said that they would not want their family to override a decision that they have made when they were alive to donate their organs and tissue after their death. With a number of respondents arguing that if families continued to be able to do this, nothing would change and being able to do this undermines the idea of having a Register and recording your wishes on it.

Under the new system, families will still be supported by the specialist nurses in personal discussions about organ donation at the bedside with the emphasis on honouring their loved one's wishes. The family will maintain a key role, not least because families provide important information to nurses and clinicians about their loved one's medical and behavioural history which allows clinicians to assess whether donation could be an option. Doctors also have duty of care to the family of the deceased and will not want to cause further upset at such a difficult time for the family.

Where the deceased has not recorded a decision on the Register, their close family and friends will play an important role in providing information to the specialist nurse if they believe that the deceased would not have wanted to donate their organs and tissues. This may be, for example, building on discussions that they have had with the deceased about donation, or their knowledge of the deceased and their generosity or attitude more generally in life.

Where there is a recorded decision on the Register to either donate or to not donate, if the family believe that the deceased's recorded decision is not the most recent one and they had changed their mind since they recorded a decision on the Register, the family will be able to provide the relevant information to the specialist nurse.

Novel and Rare Transplants

There were no comments received that indicated that they thought that novel and rare transplants should be included in the new system. With the majority of comments agreeing the Department position that novel and rare transplants should not form part of the new system.

It is the Departments intention to identify the types of organ or tissue donation that will form part of the new system. The organs and tissue that will be included with new system are kidneys, heart, liver, small bowel, eyes, lungs, pancreas and tissue.

As with the current system you will still be able to choose what organs or tissue you wish donate for transplant.

The Department will continue to monitor these areas as what is considered novel and rare currently may change with medical advancements in the future.

Research

The general consensus from the comments raised in the consultation was that organ donation for research purposes should be excluded from the new system and should require either express consent or remain as an opt-in option before being undertaken.

It is the Departments intention to identify the types of organ or tissue donation that will form part of the new system. Organs donated for research will not be included in this list and would therefore need to have express consent to enable organs and or tissues to be donated for research purposes.

Faith and Beliefs

The Department believes, as do the majority of the respondents that people’s religious, personal beliefs and values need to be considered in the organ donation process, but that the proposed new system will still give them the option to opt-out of organ donation.

To ensure that these are taken into consideration the training that is already available for specialist nurses on organ donation will be updated and extended to other healthcare staff working on organ donation. This will ensure that they are fully aware of the different religious and cultural beliefs, including the role of the family which will need to be considered as part of discussions at the bedside.

We will be working on implementation guidance for healthcare professionals setting out how the new arrangements will work in practice. This will be in the form of a Code of Practice which will be issued and monitored by the HTA. This will also set out how religious and cultural considerations will form part of discussions with the family.

Raising Awareness of the Change in Legislation

The general consensus from the respondents was that it was vital that there was a widespread advertisement and education programme in place to ensure the before the new system is implemented.

The DoH in NI already has a statutory duty· to promote organ donation, and in 2018 published a policy statement· outlining its key commitments to deliver this. The overall objective of the policy is, and remains, to promote a positive, cultural, long term change in attitudes and behaviours in relation to organ donation. The Department is working with the Health and Social Care (HSC) system, the public sector (including local government and the education system), and wider society, to promote organ donation through a coordinated and sustained programme of communication. These commitments are not impacted by the proposed move to a statutory opt-out system, and will remain in place during and after implementation of any new system.

The Department understands that the changes to how organs and tissues will be donated in the future will mark a fundamental shift from what is happening currently in NI.

Therefore, during the transition period the Department will launch a communication campaign to raise awareness – likely in the autumn of 2021. This will be a comprehensive campaign using multiple channels to achieve a wide coverage across NI. The Department wants to reach as much of the population as possible, to make people aware of how the change in the law will impact on them and to get people thinking about their organ donation decision.

Therefore the draft Bill should include a provision for specifically for the promotion and reporting on the new legislative consent framework.

Conclusion

Though great progress has been made in recent years to increase public awareness and understanding about organ donation, 10-15 people still die each year in NI due to a lack of suitable organs and there are around 115 people waiting for an organ transplant in NI that could save or transform their life.

Our ability to help those in need of transplants is limited by the rate of consent within the small pool of potential donors. We know that the vast majority of people in this country support organ donation in principle, but so far, only 49% have signed up to be an organ donor.

In light of the strong public, professional and voluntary sector support for the consultation proposals, the Department aims to proceed with a draft bill.

The Department will continue to encourage everyone to record their decision on organ donation - whether that is to donate or to not donate – through the ODR and/or by making their decision known to their family and friends. In this way, families can be certain that they are acting according to their loved one's wishes.

To ensure the new system is effective, we will launch an extensive awareness and education programme in advance of the implementation of the new system and ensure that all healthcare staff involved in the process have been adequately trained.

The Bill will also place a statutory duty on the Department in respect of promoting ongoing awareness of the new opt-out framework, and of reporting regularly to the Assembly on its impact and effectiveness. This will ensure that both present and future generations would continue to be fully informed about the legislative framework, and therefore be able to make fully informed decisions whether or not they wish to become organ donors.

Annex A

Organ Donation Soft Opt Out Consultation Consultation Engagement Plan

Date: November 2020

Prepared by: Catherine McKeown

Contents

Introduction

July 2020 saw Health Minister Robin Swann announce plans to hold a consultation on introducing a soft opt-out system for organ donation in Northern Ireland. This commitment to progressing the issue of soft opt-out for organ donation and to increase the promotion of organ donation will facilitate more organs to become available for those who need a transplant. **The subsequent change in legislation would bring us in line with the other countries in the UK.**

To ensure that the consultation engages as widely as possible with the general population of Northern Ireland, the clinical community, and government, an engagement plan for these audiences is required. Garnering maximum engagement and feedback will ensure a fit for purpose system is developed and will facilitate maximum buy-in and support for the soft opt-out system.

This document details the plan to roll-out and maximise general community engagement for the consultation. The main elements of the community engagement plan can be summarised into 3 main components:

1. Consultation launch
2. Consultation engagement activities
    - Partner and stakeholder briefings
        - HSC Trusts
        - Clinical community
        - Charity partners
        - Local Councils
    - Media
    - Political party briefings
    - Community engagement sessions
        - General public
        - Faith and cultural organisations
3. Awareness activities

It is hoped that the bulk of the engagement sessions will be able to take place within the initial weeks following the launch when it will be fresh in people's minds and they will generally reply promptly. Remaining activity will consist of regular reminders and ongoing engagement sessions.

Given the new context of operating within COVID-19 restrictions, the consultation engagement will be almost entirely a virtual delivery. With this in mind, consideration will be given to the most appropriate tool for each audience. It is likely Zoom platform will be used for the majority on engagement sessions, however this may need to be flexible.

Aims

- To ensure maximum awareness of the consultation and the process
- To secure maximum engagement with the consultation
- To ensure the consultation is as accessible as possible
- To work collaboratively with partners and stakeholders to maximise awareness and engagement
- To utilise the consultation engagement to raise awareness of organ donation

Objectives

- To employ a range of engagement activities to target a range of individuals and groups
- To deliver targeted messaging tailored to a range of audiences
- To engage on both a mass-media and a one-to-one basis with audiences
- To harness partners with messaging and tools to assist in awareness and engagement
- To use new technology and virtual techniques to counteract COVID-19 restrictions

Audiences

- General public in Northern Ireland
- Charity organisations
- Stakeholders
    - HSC Trusts –
        - Organ Donation Committees
        - Communications teams
    - HSC Board
- Politicians
- Media
- Local Councils
- Faith and cultural organisations

Plan

Consultation launch

This will consist of a media launch with press release and photo opportunity. The Minister will lead this launch and it will involve a local patient on the transplant waiting list. The emphasis of the piece will be around stark statistics of the number of people waiting for an organ transplant in Northern Ireland, and put a face to one of these. In contrast to this, the piece will then be an opportunity to lead in to the tremendous benefit that organ donation has on saving and transforming lives and hence why the change in legislation is a positive opportunity. It will also reinforce why engagement with the consultation is important to ensure that implementation of the legislation change meets with a range of views and beliefs and hence receives wide support.

Consultation engagement activities

Partner and stakeholder briefings

The purpose of briefing sessions with partners and stakeholders is to ensure that they are fully up to speed with the consultation plans and key messages, and have any relevant materials to allow them to promote on their own channels and engage with their own networks as relevant. The sessions should take place as close to the launch as possible, and will also be followed up with a supporting email with all information and assets.

Partners and stakeholders to receive briefing sessions are found below:

- *HSC Trusts*

These sessions can be achieved either through the next Organ Donation Committee meetings, or if none are planned for December then a special meeting will be requested. As the Organ Donation Committee meetings have membership from clinical leads, specialist nurses, and communications teams then these are a very useful means for briefing all relevant teams within the Trusts, particularly Communications teams.

- *Clinical community*

Working with our partners in NHSBT, they will support the engagement with the clinical community via existing networks and standing groups as well as cascading information widely. The clinical engagement will include routes such as primary and secondary care, bereavement networks, nursing routes, wider transplant community, Transplant Commissioners, intensive care routes, coroners.

- *Charity partners*

A briefing session should be arranged with all charity partners collectively. This will follow a more general update via the Charity Sub Group as to outline consultation plans and timelines. The briefing session will be an opportunity to share the briefing pack, allow charity partners to seek any clarifications they may have and to confirm their plans for promotion and engagement with their members and other audiences.

- *Local Councils*

A key to disseminating promotion of the consultation at a local level and encouraging people to engage with it will be the local councils. It is recommended that a briefing session be arranged with the key Communications contacts within each local council, and council CEOs can also be invited to attend. This briefing session will cover items as per the Trust and Charity sessions but it will also clearly outline the ‘ask’ of local councils and to ensure they are provided with the necessary tools to make this as easy as possible, for example, to support the launch messaging and the promotion of the local public awareness sessions.

Media

Working with all media outlets will be important to ensure maximum awareness of and engagement with the consultation. They will be important for the main launch of the consultation and for reminders where possible. A briefing pack will be developed to include explanatory detail of the existing and new organ donation systems, why the change in legislation will be beneficial, and how people can get involved. To help illustrate the benefits in a more powerful way, testimonials from recipients and donor families will be included.

Political party briefings

The importance of organ donation, support for the move to a soft opt-out system, and the ongoing promotion, awareness raising and education around organ donation enjoys general cross-party support in the Northern Ireland Executive. It is important to ensure this continues to be the case and that the legislation change sees safe passage through the debating and ratification stages of the NI Executive. An e-pack relating to the consultation will be emailed to all MLA’s with an invitation to avail of specific meeting if requested to discuss any queries.

Specific and ongoing engagement with political parties is an activity that will be important following the final consultation response report as it will allow updates to be highlighted, to gauge continued levels of support, and to ensure any emerging queries are closed off proactively and satisfactorily for those concerned.

Community engagement sessions

As organ donation is an issue which affects everyone in society, it is vital that the views of the general population are gathered as widely as possible to ensure that the resulting soft opt-out system implemented is met with maximum buy-in and support as it will have been developed with all views and feedback in mind.

- *General public of Northern Ireland*

Ideally, these sessions would have taken place face to face in each local Council area, but while present conditions exist, they will be delivered virtually. These may be more accessible and flexible for attendees, however we are also competing with a lot of screen time and additional at-home responsibilities at present. It will be important to link in with groups which represent older audiences or marginalised groups in case any accessibility issues are flagged, then alternatives methods of delivery can be examined.

The sessions should be run at various times of the day to maximise flexibility and ideally, targeted sessions should be delivered for key audience groups such as young and older people, faith organisations or BAME networks.

Stakeholders including local councils will be engaged to help to promote the events.

Technology is to be confirmed but it is likely that these will be hosted and delivered using the Zoom webinar platform.

Staffing required is also to be confirmed but it is recommended that the sessions are hosted/chaired by the Department, with supporting attendance to include PHA, NHSBT and HSC Trusts where possible, to form a 'panel' for the session.

An approved presentation would be developed for use at these sessions and would include background to organ donation, statistics, a summary of the current opt-in system, and explanation of the opt-out system and how it would work. The facilitators would then invite questions and comments for the panel around how best to introduce this new system. These sessions are an opportunity to correct any inaccurate myths that may exist around organ donation, and also identify any pervading trains of thought or concerns that may need to be addressed in subsequent organ donation promotion activity and messaging.

Sessions would be recorded (making participants aware of this) and any pertinent feedback or comments documented.

- *Faith and cultural organisations*

The same approach to the above will be taken however all faith and cultural organisations will be contacted directly to inform them of the consultation and offer a specific and individual session to allow presentation content and context to be amended so ensuring they are sensitive to and cognisant of particular beliefs.

Awareness activities

Social media (PHA lead with partner support) will be the main vehicle for communicating information about the consultation and the engagement opportunities. It will encourage and remind audiences to make a response, and drive people to the online response platform and will continue for the duration of the consultation period. A schedule of social media content will be prepared once all activities and online events are confirmed and these can be amplified on NHSBT and partner channels.

Preparedness

It will be important to consider some strategies to deal with any negative effects stemming from the consultation process and move to soft opt out system. Negative effects can include increases in opt-outs from the Organ Donor Register, negative narratives from groups or individuals, or indeed fake news. This is something that both England and Wales experienced during their respective consultations and legislation change campaigns.

Strategies to deal with these instances will include media monitoring and social listening, comprehensive lines to take, and ensuring stakeholders are well briefed and communicated with throughout as they will act as valuable third party advocates who can more easily and independently correct any inaccurate viewpoints or narrative.

Assets to be developed

- Partner/stakeholder briefing pack, to include:
    - Press release
    - Purpose of the consultation
    - Explanatory detail of existing and new organ donation systems
    - Key messages
    - Lines to take
    - Link to response platform
    - Social media assets
    - Testimonials

- MLA e-pack

- Designed and approved presentations, tailored as needed to different groups and audiences

Timelines

High level timelines

Late Nov/early Dec 2020	Main launch
1 December 2020 – 19 February 2021	Consultation period
22 February – 16 April 2021	Processing responses, finalising policy
May 2021	Legislation approval process commences
Winter 2021 – May 2022	Awareness campaign
May 2022	Legislation live

Monthly timelines

December	Main launch Political party e-pack Partner briefing sessions
January	Community engagement sessions Social media activity (Launch: campaign is live/engage now)
January	Community engagement sessions ongoing Social media activity (Reinforce: info sessions/have your say)
February	Community engagement sessions ongoing Social media activity (Remind: consultation closing/don't miss having your say)

Annex B

List of Organisations

Please see below list of Organisation that responded to the consultation.

Altnagelvin Renal Support Group
Belfast Health and Social Care Trust
Belfast Islamic Centre
British Heart Foundation Northern Ireland
British Medical Association Northern Ireland
Cambridge Innovation Institute
Children's Heartbeat Trust
Children's Liver Disease Foundation
Church and Society Commission of the Church of Ireland
DERG VALLEY HEALTHY LIVING CENTRE
Donate4daithi
Education Authority
General Medical Council
Haemochromatosis UK
Health Ethics and Policy Research Group at Lancaster University
Human Tissue Authority
Kidney Care UK
Live Loudly Donate Proudly
Mid Ulster District Council
Newry and Mourne District Council
NHS Blood and Transplant
NHSBT Liver Advisory Group
NI Kidney Patients' Association
Northern Health and Social Care Trust Organ Donation Committee
Northern Health and Social Care Trust Organ Donation Committee
Northern Ireland Humanists
On Behalf of N Ireland Chairs of Organ Donation Committees
Opt for Life (Organ Donation Trust)
Royal College of General Practitioners Northern Ireland
Royal College Of Nursing
Royal College of Physicians
Royal College of Surgeons (England) in Northern Ireland
RVH Liver Support Group
SDLP
Sinn Fein
The Christian Institute
The Alliance Party
Western Health and Social Care Trust

This Annexe details a sample of some of the comments made by respondents.

Themes	Questions	Comments
Your Organ Donation Decision	Respondents were asked if they would be willing to donate their organs and / or tissue after their death [under the current legal system of consent in Northern Ireland] and if so had they already recorded their donation decision, e.g. by joining the NHS Organ Donor Register or otherwise. If respondents answered 'yes' to the above, they were then asked if they shared their decision with loved ones; and would a move to a statutory opt-out system change their decision regarding organ donation.	**"I fully support organ donation however feel the current opt in legislation makes it easy for consenting adults to forget to sign up and therefore reduces the number of organs donated. Opt out legislation may encourage more conversations around organ donation as well."** **"Organ donation can be life changing and life saving for patients on the transplant list. It can also be a tremendous sense of comfort and pride to the families of donors. It contributes to their legacy. We should maximise legislation to facilitate this process."** **"I do believe that without this legislation there will be potentially more and more unethical transplants to NI citizens as they are so desperate they will travel abroad and purchase organs on the black market from people forced to sell their organs to provide for themselves of their families. Please, please help NI citizens help each other."** **"I think this proposal is brilliant and hope it passes. I think most people would agree with organ donation but the current registration process is not enough and requires people to actively go looking for how to do it. With opt out process, majority are opted in and anyone with strong beliefs not to be a donor, will actively do so or have it written in their will."**

Themes	Questions	Comments
		“I do agree with organ donation and am constantly disappointed that more people do not sign up. However, IDO NOT agree with government introducing an opt-out system. It is each person's choice what happens to their body after death, we should not have to remember to Opt-out! I feel very strongly about this.” “Nobody has a right to an organ donation - it is a gift, not a right and this opt out charade is nothing less than a disgraceful, sneaky, under-hand attack on peoples civil liberties. The nanny state taking control of people’s lives and dressing it up as being something for every ones good.” “I personally have an aversion to donation. I would not agree to have my remains used in this manner and I disagree with changing the law to allow it. An individual's right to choose needs to be kept on the Statute book.”

Exemptions to Opt-Out Legislation	Respondents were asked to what extent they agree that opt-out legislation should NOT apply to children (those under 18 years) and that the donation decision should be made by those with parental responsibility.	***"Anyone under the age of 18 should be donors only with explicit consent from those with parental responsibility. Individuals under the age of 18 should continue to have an opportunity to actively register their wishes on the organ donation register so that families can be informed if a decision has been recorded and they can take this into consideration."***
		"In regards to the question around parental consent, I answered no as I believe it should be 16. By 16 a person has the capacity to make an informed choice to opt out." ***"It is perfectly conceivable that teenagers should be consulted on becoming organ donors. Giving them the appropriate knowledge will lead to a sufficient understanding and competence of what is involved in the opt-out process for a teenager."*** ***"Some members considered that from the age of 16 individuals are capable of meaningful exploration of complex decisions, including that of donation. Such choices could be given weight with parents consulted rather than having sole decision making responsibility."***
	This question asked respondents if certain people should be exempt from deemed consent for organ donation; and the family should provide that consent.	***"While we support a statutory opt-out system, it is of course the decision and right of individuals to opt-out for their own reasons. We think it is therefore important to have certain groups excluded within any legislation that is developed, and to make it very clear and widely publicised that anyone with strong personal views who fall outside of these categories can choose to opt-out. "*** **"By having an option to register an opt-out there is no need for special exceptions or clauses about age, religious faith, etc. Anyone who disagrees with organ donation on the basis of**

		those factors can opt-out. The only exception I see if for those who are incapable of making decisions for themselves, through illness or age etc. but in those cases their guardians can opt-out for them if that's a problem." "Capacity is decision specific. So, a person may lose the capacity to decide whether or not they would have chemotherapy, but have the capacity to choose cornflakes for breakfast. However, this type of decision is likely to be steadfast, and not one which the person would like to think they had reneged on. If I were to take dementia / brain injury, I still want to donate. That I have lost the capacity to make this decision, does not mean I have changed my mind."

The role of the family & loved ones	In response to what extent respondents agree that, in situations where there is a known decision to donate recorded on the NHS Organ Donor Register, the family should always be asked about the last known organ donation decision of their loved one, to ensure it's still accurate.	**"Family will always have a tough time making the decision to donate organs of their deceased loved ones, the automatic opt-in would save those difficult decisions and anguish - while giving them comfort many lives can continue with the organs of their loved one."** **"In addition, I believe that during the period immediately after death, the deceased family is not in the right frame of mind to make such a decision, and furthermore, having such a question imposed on them is an undue and unnecessary burden."** **"We would also like to emphasise that under an opt out system, the family discussion remains an essential part of the end-of-life care decisions. The family involvement in the donation consideration is essential to ensure that the last known decision of the individual is determined, as well maintaining trust in the system. It is also essential for assessing whether organs are suitable for transplantation."** **"Family should never be allowed to overrule a decision already made by the person who decided and registered to donate."**
	Respondents were further asked to what extent they agree that, in situations where there is no known organ donation decision, the family should always be asked about whether their loved one would have objected to organ donation.	**"I believe the family should be asked out of courtesy but I don't necessarily believe their word or say should be taken into consideration if there is no opt-out completed on the donor register. I would view that as consent. It is a personal responsibility to keep your donor register up to date whether it's the current opt-in or a future opt-out."** **"I strongly believe when the opt out system comes into play that family should not be able to change the decision that was formerly made."**

		“This legislation will also take the decision out of relatives’ hands to over-rule a donating decision that was already made by the person who is dying.”
Novel & Rare Transplants	Respondents were asked to what extent they agree that organs and tissues that could be used for rare or novel types of transplantation (e.g. limb or face) should be excluded from opt-out legislation.	**“We understand and support the rationale for the exclusion of specific organs and tissues from deemed consent. Our supporters with whom we have engaged on this question urge the Department to revisit this area in the future as transplants which are considered rare or novel today may, through continued advancement of knowledge, become more mainstream in the future.”** **“The face is very important to many as a symbol of the deceased back when they were alive. So regardless of how I have answered in the questionnaire I would say that the face would be one of the biggest considerations to be double checked on or be opt in. I think limbs and many other external donations wouldn't be viewed as negatively.”** **“I believe that only major organs should be included in the initial proposal and that novel or rare donations e.g. face/limbs should be an opt in system.”**

Research	Respondents were asked to what extent do they agree that the donation of organs and tissues for research purposes should be excluded from statutory opt-out and the family approached for express consent.	**“Many of us are old enough to remember the Alder Hey organ retention scandal, and that has damaged the public perception of retaining organs and tissues for research. It's damaged trust. And that's where the practice of asking families comes in. An opt-out system will only work if people trust the system to do what it says it's going to, and where people lack that trust, it's partly about ignorance, but we have to acknowledge that things have been done wrong, and continue to be done wrong, that make it very hard for some individuals and communities to trust the system.”** **“Organ donation for research should continue to be opt-in.”** **“While donations in the interest of research are very important, we believe that these should be separate conversations and decisions outside of the statutory opt-out.”**

Faith & Beliefs	This question asked to what extent do you agree that people's faith or beliefs should continue to be taken into consideration as part of the donation discussion after any move to an opt-out system.	**"Faith and belief, for many, are central to the decision to help others through Organ Donation. We recognise that the social and moral teachings of many faiths promote voluntary donation of an organ or organs for the good of others as an act of generosity."** **"The Gift of Life is recognised by many faiths as saving and transforming lives and we fully support the continued involvement of faith or belief in the donation discussion and indeed in the honouring of decisions made in life."** **"We strongly believe in and defend the right to freedom of religion or belief. Therefore, we agree that a person's religion or belief should be taken into consideration following any move to an opt-out system. We propose a system similar to England, whereby upon completion of the registration process, persons can state that their religion or beliefs are important to them in making this decision."** **"We strongly support the proposal that the current commitment to honouring an individual's decision regarding faith/beliefs and the support and advice available to families should be continued after the move to opt-out."** **"Obviously an organ to be transplanted is only of use while it is alive, and can only be taken after the donor is deemed to be dead. Religion has to do with life, death and what happens after death, many religious people would have issues about the State deciding when a person has died. An opt-out system increases the risks that people's genuine conscientious objections are ignored."**

Raising awareness of the change in legislation	Respondents were asked to select three options as to what they thought was the most important and effective activity for raising awareness of the law change.	**"Any publicity campaign should make use of those waiting, those who have had a transplant and most importantly relatives who have given permission for donation."** **"You need to incorporate into the secondary curriculum (perhaps as part of Personal Development Education). Keep it separate from religion education lessons. Including it in curriculum will help open discussion at the dinner table with family. Could it be made part of a questionnaire with employers? Part of an occupational health check?"** **"Other places to advertise - people's pay slips, especially the HSC payslip, part of it could be reformatted to include inviting people to take part in this survey. Work with the HSC to get a global circular email sent to HSC staff to participate in this with a "forward" /invite others button."** **"Essential to start early i.e. in schools. My own kids always came with me when I donated blood and I have always talked about organ donation, they are now adults, donate blood and are registered donors."**
	Respondents were asked If they have any comments or views they would like to express in relation to the Equality Screening, Disability Duties and Human Rights Assessment Template or Rural Screening Document that accompany this consultation document and can be found at https://www.health-ni.gov.uk/consultations/organ-donation, please comment below.	**Comments for the change** **"I believe that organ donation should be compulsory as the right to life, as per Article 2 of the Human Rights Act, of one person and perhaps several people, must always outweigh any wishes of one deceased person and/or their family."** **"I think it would increase the number of successful organ donations. It could potentially save a lot of lives but people's rights are still being protected as they can opt out. It would also give people the chance to speak to family and loved ones about**

		the topic of organ donation when they pass. I think that the donor list would increase immensely which will give the gift of life to others.”
		<u>Comments against the change</u> **“I am completely opposed to this proposed change in law as it is completely unethical as shown by some of the questions posed in this survey.”** **“Nobody has a right to an organ donation - it is a gift, not a right and this opt out charade is nothing less than a disgraceful, sneaky, under-hand attack on peoples civil liberties. The nanny state taking control of peoples lives and dressing it up as being something for every ones good.”** **“I will not be coerced in this underhand way and will simply opt out then also instruct my solicitor to put it in my will that under no circumstances are any of my body parts to be used for any donation purposes, thus preventing the back-door harvesting of any of my organs through the false, unjust and downright dishonest method of using family relatives who may have different opinions to me and over-riding my true wishes.”** **“The system should be left as it is as the proposed new system is clearly more open to abuse and manipulation. As I said, no-one, regardless of their health situation has a right to someone else’s organs, these are gifts and should be left that way. Obviously the majority of people feel that way as if they didn't then you wouldn't be trying to manipulate the system. Shame on you. This is a clear attempt to subvert peoples Human Rights by enforcing something on the majority of people that only a**

		minority support. Unfair and undemocratic. Nanny state taking control, trampling over peoples true wishes and legitimate concerns.” “I am totally opposed to having to opt out in order to stop someone stealing my organs. I would regard it as theft when I have not given permission. I have to give consent for things such as surgical procedures or medical treatment yet under this legislation consent is not required - totally appalling. There is no law change. Obvious that it is going ahead no matter what people think. I believe an opt out system would have implications for my human rights under article 9 of the Human Rights Act.”

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