

EQUALITY IMPACT ASSESSMENT - RESULTS

Title of Policy	Human Tissue (Authorisation) (Scotland) Bill
Summary of aims and desired outcomes of Policy	The Human Tissue (Authorisation) (Scotland) Bill will provide the legislative basis for a soft opt out system of organ and tissue donation.
Directorate: Division: team	Directorate for Population Health: Health Protection Division: Organ and Tissue Donation Bill Team

Executive summary

A full EQIA was carried out to assess the impact of the Human Tissue (Authorisation) (Scotland) Bill. This has identified impacts for Age, Race/Ethnicity, Religion/Belief and Disability protected characteristics.

The EQIA process has demonstrated that none of the proposals are discriminatory and that it will not be necessary to make any specific amendments to the proposed soft opt out system as given effect to by the Human Tissue (Authorisation) (Scotland) Bill.

The proposed system has been developed taking into account the needs of equalities groups and specific mitigating elements have been incorporated where necessary. More broadly, on-going awareness raising work regarding donation and also future awareness raising specifically regarding the opt out system will be important in explaining what choices people will have and also in helping to increase understanding and support for donation more broadly which will help mitigate against any potential negative impacts.

Background

Organ and tissue transplantation can save and significantly improve lives, but at present there are insufficient donors to meet the number of organs needed by people on the transplant waiting list, as well as the need for some forms of tissue transplants.

Through our plan, A Donation and Transplantation Plan for Scotland 2013-2020 and the work of the Scottish Donation and Transplant Group we have already made good progress in increasing organ donation and transplantation in Scotland over recent years, with an 89% increase in the number of people who donated organs after their death in Scotland between 2007-08 and 2017-18.

However despite all this activity and improvements made so far, there are still over 500 people on the active transplant waiting list in Scotland, waiting for an organ. It is important therefore to look at ways in which we can potentially increase the proportion of cases where organ and/or tissue donation is authorised, including moving to a soft opt out system.

Currently, donation and transplantation in Scotland is underpinned by the Human Tissue (Scotland) Act 2006. This legislation sets out the legal basis for authorisation of donation for transplantation, as well as a range of provisions relating to other aspects of donation and transplantation. The legislation provides that organs and tissue can only be donated from someone if either the person themselves authorised donation before they died or if their nearest relative, or person with parental rights and responsibilities in the case of a child, authorises the donation on their behalf at the point of death – this is known as an opt in system.

Following a public consultation, the Scottish Government is introducing the Human Tissue (Authorisation) (Scotland) Bill to

provide for a soft opt out system of organ and tissue donation. The proposed soft opt out system will mean that a person can continue to register a decision to donate or not to donate. In cases where a person does not register a decision they may be deemed to have authorised donation if they die in circumstances which would allow their organs or tissue to be donated.

However, it is important to ensure that there are safeguards in place. When a person is potentially deemed to have authorised donation, those working in donation would be required to check with any potential donor's family members about any views the potential donor held on donation. This would mean for example that where a person had not opted out of donation, but family members advise of an objection the deceased held, the donation wouldn't proceed. More broadly, the Bill provides for a framework where the views of the potential donor take precedence, which will mean in all circumstances it should be the views of the potential donor, where they are known, which determine whether donation goes ahead.

In addition, certain groups of people would require explicit authorisation, either from themselves during their lifetime or from a nearest relative, or person with parental rights and responsibilities in the case of a child, upon their death. This would include children; adults resident in Scotland less than 12 months; and adults without the capacity to understand deemed authorisation.

Moving to a soft opt out system of donation will add to the package of measures already in place to increase donation and will be part of the on-going long term culture change to encourage people to support donation.

The Scope of the EQIA

This assessment focuses on the impacts of the specific changes to authorisation, rather than the potential impacts on transplant recipients.

The likely impacts of the legislation were assessed by identifying existing evidence, analysing potential impacts and testing these with analytical and wider policy colleagues. They were also considered through the public consultation and through further engagement with specific groups which would be affected by the proposals. This included focus groups facilitated by the Scottish Health Council with young people, young people with experience of being looked after, and people with learning difficulties to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed. Issues were also explored with representatives of several faith groups which responded to the consultation.

Discussions about the impacts were also held with a sub group of the Scottish Donation and Transplant Group which has been considering the proposals for a soft opt out system more broadly. In addition, discussions have been held with those in the field of donation and transplantation with particular responsibility for increasing donation from ethnic minority communities.

The consultation on increasing organ and tissue donation, which included proposals for a soft opt out system, asked respondents about particular impacts or implications of the proposed changes on equalities groups. Just over half of organisations (55%) and around a fifth of individuals (18%) said they could identify impacts or implications for particular equalities groups.

Religion was the focus of most comments about negative impacts for equalities groups. Respondents stressed the importance of promoting the right to opt out, and working with faith groups to

ensure this message was effectively communicated. Those who offered more detailed comments identified three main issues: that some people may be opposed in principle to donation 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 would be incompatible with the beliefs of such groups or would risk donations being deemed in situations where an individual was opposed for religious or cultural reasons.

Other protected characteristics highlighted in the responses included 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. Additionally respondents identified 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.

Hard to reach or socially disadvantaged groups which included some protected characteristics were also identified such as young people, older people and recent migrants. Additionally, some respondents queried whether there would be implications for LGBT people.

More broadly, respondents highlighted the importance of consulting equalities groups, the need for public information to take account of specific needs, and for those involved in donation to take account of the needs or views of different equality groups.

Key Findings

The EQIA process identified that there would be impacts for the following protected characteristics:

- Age
- Race/Ethnicity
- Religion/Belief
- Disability

Some responses to the consultation queried whether there would be implications for LGBT people, however this was discounted at the screening stage as no impacts were identified for this group as a result of the change to an opt out system.

Age

This assessment considers different age groups across the age range, in particular children and young people and older people. There is no direct evidence of the impact of opt out systems on different age groups or children.

Children/Young People

The provisions in the Bill provide a balance between safeguarding and enabling children's rights, in line with the principles of the United National Convention on the Rights of the Child. The opt out system includes a safeguard whereby children (under 16) will not be subject to deemed authorisation and instead authorisation will need to be explicit, in recognition that they may not understand the need to opt out if they do not wish to become a donor. Those aged 12 and over will continue to be able to authorise donation as they can now, and new provisions will enable them to make an opt out declaration.

A new provision will recognise the views of children aged under 12. The changes would have a positive impact on children

under 12 in recognising that a child, whilst unable to legally authorise donation or make an opt out declaration, may have views on organ and tissue donation. The change would introduce a new requirement, in line with that for children aged over 12 and adults, for those authorising donation to take account of the potential donor's views. This is in the form of a barrier to donation where the authoriser is aware that the child would have been unwilling to donate.

Young people aged 16 and over are classified as 'adults' in the legislation and will therefore be subject to deemed authorisation. The legislation contains safeguards to prevent those people who do not wish to, from becoming a donor, even if they haven't recorded an opt out decision. Family members will be able to advise of any objection to donation the potential donor held, meaning donation wouldn't proceed. Importantly the aim of the legislation is to give effect to the wishes of the potential donor in all circumstances, which means the young person's views would take precedence over the views of family members.

A change is also being made to the current legislation to optimise the potential for the donor's views to be known and adhered to. When authorisation is being given by, in the case of a child, a person with parental rights and responsibilities, they will be required not only to take into account their own knowledge of the child's unwillingness to become a donor but any relevant information from other people e.g. family members or friends.

It will be important that the awareness raising campaign takes account of the needs of children and young people. It will be important that young people are notified as they approach age 16 that they will potentially be subject to deemed authorisation if they haven't recorded a donation decision. The focus groups with young people have helped to identify which methods of communication are preferred and will feed into the overall awareness raising strategy.

Additionally, the Scottish Government has developed an internationally recognised schools educational resource pack to increase awareness of organ and tissue donation amongst school pupils from age 12 and above. The pack will be updated to take account of the changes and will be a useful resource to continue to raise awareness under the opt out system and educate young people about how deemed authorisation would apply to those aged 16 and over.

The Bill includes provision to enable a Local Authority, in the absence of a donation decision made by the child, to make a donation decision on behalf a child for whom it holds parental rights and responsibilities. A focus group and small survey with care-experienced young people were carried out to hear their views on the proposal. Those in the focus group had mixed views on who was most appropriate to make a decision on donation and the discussion reflected the differing individual circumstances and need for flexibility in any approach. Those responding to the survey were supportive of allowing a local authority to authorise donation and had mixed views on whether views should be sought from others to inform the donation decision.

In order to take account of the varying individual circumstances as identified in the focus group, the Bill will require that, in deciding whether to authorise, the Local Authority would be required to take into account the views of other people. This will firstly include the child's views, and also those of other relevant parties, including the child's parents. The changes would have a positive impact for children, particularly those under 12, as they are unable to authorise their own donation so currently, where the Local Authority holds parental rights and responsibilities, donation could not proceed even if it was the child's stated wish.

Older People

Some consultation responses identified that older people may be part of a hard to reach group and might be less likely to know about or understand an opt out system. It will be important that the awareness raising campaign takes account of the communication needs of this group, by for example utilising print media. There is flexibility about how donation decisions may be recorded and additionally an Organ Donor Register telephone helpline may be helpful for this group to enable them to register donation choices over the phone if they wish to, rather than doing so online.

Race/Ethnicity

There are impacts for two different groups of people – people from ethnic minority communities and people newly resident in Scotland.

No direct evidence of the impact of moving to an opt out system on ethnic minority groups was identified. More broadly, evidence shows that some ethnic minority communities generally have a higher need for transplantation (primarily of kidneys) than the population as a whole. This is significant, as the best match for a kidney is from someone within the same ethnic group, consequently ethnic minority patients on average face longer waiting times for transplants. People from ethnic minority communities are also much less likely to be registered donors and upon death their loved ones are less likely to authorise donation.

Moving to an opt out system has the potential to positively impact ethnic minority groups as it aims to encourage a culture change to encourage people to support donation and assumes that people are willing to donate unless they have opted out – this may help to increase the number of authorisations from ethnic minority communities. However there are a range of

specific factors that relate to ethnic minority groups having lower levels of authorisation, including poorer knowledge about donation, less positive attitudes, and greater concerns around organ and tissue donation in general, which could affect the extent to which a move to a soft opt out system will affect change within these communities. Therefore it is important that current work continues to promote awareness and support for donation within ethnic minority communities, takes account of the change to an opt out system and seeks to allay concerns that communities may have.

The Scottish Government has been working with Kidney Research UK which trains volunteers from ethnic minority communities to become peer educators to increase awareness of kidney disease and organ donation. This work, along with that of those within the donation workforce with specific responsibility with regards to ethnic minority communities, will continue and will be important in promoting understanding and awareness of the change to an opt out system among ethnic minority communities.

The system provides a protection for adults who are newly resident in Scotland, to reflect the fact that a person who has only relatively recently moved to Scotland cannot reasonably be expected to have a sufficient awareness and knowledge about the operation of the opt out system to understand the implications of not opting out. Those who have been resident less than 12 months will not be subject to deemed authorisation and will instead require explicit authorisation, either from themselves or from a nearest relative. Additionally, information can be provided by others, for example friends, about the potential donor's views on donation which will also help to determine whether donation can ultimately be authorised.

It will be important that the awareness raising campaign takes account of the needs of people who don't speak English, or speak little English, by providing information in different languages.

Religion/Belief

Although there is some research exploring the role of religion in organ donation in general, there is less evidence about the impact of religion on views relating to opt in versus opt out systems of donation. One study of note explores the views of UK faith leaders, highlighting clear support for an opt in system because they perceive that it respects individual choice. A survey study of Western Muslims also explored this issue and found that 26% of respondents agreed with the concept of presumed consent, compared with 55% who did not .

More broadly, evidence shows that religion is likely to be a key influence on decisions about organ donation, although the impact is likely to vary within and between religious or faith groups. In addition to differences between religious or faith groups, there is often a lack of consensus within these groups on the issue of donation. Although the official positions stated by each of the key religious groups in the UK are broadly supportive, and none formally oppose donation, religion is still often viewed as a barrier by some as individuals are often uncertain about whether donation is supported by their faith.

There is some evidence to suggest that barriers relate more to knowledge and understanding of the processes involved, than to religious or cultural factors per se and that the importance of a specific barrier is likely to vary by religious and ethnic group. A lack of knowledge about the point at which organs are taken for example, can lead to cautious attitudes towards donation, particularly in light of the role of burial traditions and practices relating to honouring the dead and experiences of bereavement.

NHS Blood and Transplant (NHSBT) produces leaflets for all the major religions to explain the views of that religion on donation. As well as this, the work carried out amongst ethnic minority communities is done primarily through faith networks. We will continue to use our links with these networks to raise awareness

about donation more broadly and the opt out system. Additionally, in our engagement with faith groups we have made contacts to help disseminate factual information about the move to an opt out system. Information being provided in this way via a trusted source within the faith is helpful in demonstrating credibility.

Through the consultation process and our further engagement with faith groups it has been clear that there is a need for donation to continue to be seen as a gift and for people to choose to donate. One of the principles of the proposed soft opt out system is that people will still be able to opt in if they wish and awareness raising campaigns will still encourage them to do so. Additionally, in the context of high profile awareness raising campaigns about the need to opt out if a person does not wish to become a donor, it will be possible to view the absence of such an opt out decision as a wish to become a donor. These aspects, as well as the ability for family members to advise of any objections the potential donor held will mean that donation won't proceed where a person would have been unwilling to donate, which will maintain the concept of donation as a gift.

As the evidence suggests, the point at which death occurs is an important factor in decision making about donation for some people of particular faiths. An individual's religion is currently taken into account in the palliative care pathway, of which donation is a part, and this will continue under the soft opt out system. However, moving to an opt out system may prompt some people to opt out of donation for fear that donation might not be permitted depending on the type of death (circulatory death or diagnosis of death following neurological criteria). The Bill includes specific provision about the particular circumstances of death which will mean that in all cases – whether a person has opted in, opted out, or is deemed to have authorised donation, it may only proceed where it is consistent with that person's views.

Disability

No evidence was identified with regards to organ and tissue donation and disability.

There are impacts on some people with disabilities with regard to two issues: how the system operates in relation to people without capacity to understand the opt out system, and how the awareness raising campaign takes account of the needs of people with disabilities.

The soft opt out system includes a safeguard to ensure those people without capacity to understand the system are not subject to deemed authorisation. Instead explicit authorisation will be required from this group of people either from themselves in their lifetime or from family upon their death. In the case of the family being asked to make a donation decision at the point of death, there is an extra protection for this group, in line with the principles of the United Nations Convention on the Rights of People with Disabilities, which requires that any known wish of the individual is taken into account when making that decision on their behalf. Additionally, information can be provided by others, for example friends, about the potential donor's views on donation, which will also help to determine whether donation can ultimately be authorised.

Some consultation responses queried whether moving to an opt out system may lead to a culture in which the retrieval of organs is prioritised over treatment which could impact negatively upon people with disabilities, long term or life-limiting conditions. Under an opt out system the care and treatment given to patients will remain the priority of clinical staff. Donation is only raised by clinical staff when it is clear that nothing more can be done for a patient and the family has come to terms with that; this approach will continue under the opt out system. Under the current system, different clinical teams deal with treatment to those which deal with donation and transplantation

to ensure there is a separation and no perceived conflict of interest; this will continue under the opt out system.

The focus groups held with people with learning difficulties demonstrated a view that where possible people should be supported to make an informed decision about donation rather than it being assumed they can't make a decision due to a learning difficulty or other form of incapacity. The focus groups identified which ways are most effective to communicate with people with learning difficulties and other forms of incapacity. It will be important that the awareness raising campaign takes into account the needs of this group, by for example using easy read formats to help support those with learning difficulties to make informed decisions. It will also be important that the awareness raising campaign materials are accessible and take account of the needs of people with disabilities, such as those with visual impairments or those who are hard of hearing.

Recommendations and Conclusion

The EQIA process has demonstrated that none of the proposals are discriminatory and that it will not be necessary to make any specific amendments to the proposed soft opt out system as given effect to by the Human Tissue (Authorisation) (Scotland) Bill.

Impacts on equalities groups have been considered throughout the development of the proposed soft opt out system and mitigating elements have been incorporated where necessary. These include not applying deemed authorisation to certain groups of people on the basis that they might not reasonably be expected to have sufficient awareness, knowledge or understanding about the operation of the opt out system to understand the implications of not opting out. This is balanced with a continuing ability for people (aged 12 and over) in these groups to make a donation decision if they wish.

The Bill provides for a framework where the views of the potential donor take precedence, which will mean in all circumstances, including deemed authorisation, it should be the views of the potential donor, where they are known, which determine whether donation goes ahead. Additionally, specific provision about the circumstances of death will ensure that donation only proceeds where it is consistent with the person's views, which seeks to address the needs of those who would be opposed to donation following certain circumstances of death, for example on faith grounds.

More broadly, the public information and awareness raising work about the opt out system will be extremely important in explaining how the system will take account of the needs of equalities groups and the choices people will be able to make about donation. It will also be crucial that it meets the communication needs of different equalities groups, which will be informed by the consultation responses and the in-depth qualitative research. This work will be in addition to the on-going awareness raising work about donation in general, which will continue to help increase understanding and support for donation.

Fairer Scotland Duty

Summary of aims

Currently, donation and transplantation in Scotland is underpinned by the Human Tissue (Scotland) Act 2006. This legislation sets down the legal basis for authorisation of donation for transplantation and other purposes. The legislation provides that organs and tissue can only be donated from someone if either the person themselves authorised donation before they died or if their nearest relative authorises the donation on their behalf at the point of death – this is known as an opt in system.

The Human Tissue (Authorisation) (Scotland) Bill will provide for a soft opt out system of organ and tissue donation for adults. The proposed soft opt out system will mean that a person can continue to register a decision to donate or not to donate. In cases where a person does not register a decision they may be deemed to have authorised donation for transplantation if they die in circumstances which would allow their organs or tissue to be donated, subject to certain safeguards.

Moving to a soft opt out system of donation will add to the package of measures already in place to increase donation and will be part of the on-going long term culture change to encourage people to support donation.

This assessment focuses on the impacts of the specific changes to authorisation, rather than the potential impacts on transplant recipients.

Summary of evidence

The consultation sought views on any impacts there would be on equalities groups as a result of moving to an opt out system . In the responses some 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.

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 included homeless people; prisoners; recent

immigrants; those with poor English; those with low reading / literacy skills; and those less likely to have internet access.

In addition focus groups were held with young people, young people with experience of being looked after, and people with learning difficulties to understand what they thought about particular elements of the proposals and how the change should be communicated to people. The groups highlighted the need for communication methods to be inclusive, for example so as not to exclude people who do not have internet access or those who were homeless.

There is some data from the evaluation of organ donation marketing campaigns which suggests that those in the lowest socio-economic groups are somewhat less likely to wish to add their name to the Organ Donor Register than other groups, although campaigns are successful in encouraging people in these groups to join.

Summary of assessment findings

In order to ensure as broad access as possible, and not disadvantage people who do not wish to join the Organ Donor Register, the Bill provides for flexibility in how decisions to opt in or opt out are recorded, meaning that decisions can simply be written down. This is in addition to being able to be recorded on the Organ Donor Register, which can be done online, by telephone or by post.

As well as children, certain groups of adults wouldn't be subject to deemed authorisation and would instead require explicit authorisation, either from themselves during their lifetime or from a nearest relative. This would include adults resident in Scotland less than 12 months; and adults without the capacity to understand deemed authorisation, both categories which are likely to include some of those at socio-economic disadvantage.

Additionally, those working in donation would be required to check with any potential donor's family members about any views the potential donor held on donation. This would mean for example that where a person had not opted out of donation, but family members or friends advise of an objection the deceased held, the donation wouldn't proceed. More broadly, the Bill provides for a framework where the views of the potential donor take precedence, which will mean in all circumstances it should be the views of the potential donor which determine whether donation goes ahead.

In the very small number of cases where a potential donor has no relatives, friends or other person they had known for a long time who are available to be consulted, donation would not normally proceed. This is because, as well as providing information as to the potential donor's views on donation, there is a need to check their prior lifestyle history to ensure their organs are likely to be safe to transplant.

It is intended that ahead of the opt out system coming into force there will be an awareness raising campaign for at least 12 months to inform people about the new system, and the implications of not recording a donation decision in a deemed authorisation system. It will be important that this awareness raising campaign takes account of inequalities in access to information to ensure as wide a reach as possible. Campaign tracking and evaluation will incorporate analysis that looks at awareness raising performance based on socio-economic groups.

Decision

The soft opt out system as given effect to by the Human Tissue (Authorisation) (Scotland) Bill has no detrimental impact on inequalities. It includes safeguards to protect vulnerable groups and also safeguards which enable the potential donor's views to determine whether donation goes ahead even where no donation decision has been recorded. It will be important that

the awareness raising campaign takes account of inequalities in access to information to ensure as wide a reach as possible.

Sign off

Name: Gareth Brown

Job title: Deputy Director, Health Protection Division