

Human Tissue (Authorisation) (Scotland) Bill

Children's Rights and Wellbeing Impact Assessment (CRWIA)

June 2018

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Executive Summary

The Human Tissue (Authorisation) (Scotland) Bill provides for a soft opt out system of organ and tissue donation for adults (aged 16 and over) and makes some changes to the process for authorising donation by children. A full CRWIA was carried out to assess the impact of the Bill on children and young people.

The Bill has been developed in line with UNCRC principles of advancing children’s rights and aligning the approach where appropriate with that taken for adults. The provisions in the Bill provide a balance between safeguarding and enabling children and young people’s rights. There are various new provisions which will affect children and young people under 16, including:

- Enabling a child aged 12 to 16 to make an opt out declaration which will have legal effect.
- A duty to inquire about a child’s most recent view on donation, including whether they would have been willing to donate in the specific circumstances of death.
- Requirement for those authorising on behalf of a child to take into account knowledge of unwillingness of the child to donate (new for under 12s).
- Enabling a local authority to authorise donation for a child for whom it holds parental rights and responsibilities (PRRs).
- Enabling an adult with a close relationship with a child to authorise donation for a child for whom there is nobody with PRRs or they have lost capacity to take a decision on donation.

There are various new provisions which will affect children and young people aged 16 to 18, including:

- Enabling an adult to make an opt out declaration which will have legal effect.
- Introduction of deemed authorisation, where an adult has not recorded a donation decision.
- Protections for those without the capacity to understand deemed authorisation or those resident in Scotland less than 12 months, who would require explicit authorisation.
- A duty to inquire about the adult’s most recent view on donation, including whether they would have been willing to donate in the specific circumstances of death.
- Requirement for those authorising on behalf of an adult to take into account knowledge of unwillingness of the adult to donate.

	<p>One of the Bill’s overarching principles is to give precedence to the views of the potential donor, which will mean in all circumstances and for people of all ages it should be the views of the potential donor which determine whether donation goes ahead, where they are known.</p> <p>Focus groups with young people and young people with experience of being looked after were undertaken to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed.</p> <p>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 have, and supporting children and young people to make informed decisions about donation.</p>
<p>Background</p>	<p>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 tissue transplants.</p> <p>Through our plan, <i>A Donation and Transplantation Plan for Scotland 2013-2020</i> and the work of the Scottish Donation and Transplantation 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.</p> <p>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.</p> <p>Currently, donation and transplantation in Scotland is underpinned by the Human Tissue (Scotland) Act 2006 (the 2006 Act). This legislation sets down 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 a family member authorises the donation on their behalf at the point of death – this is known as an opt in system.</p> <p>Under the current legislation children aged over 12 and under 16 can authorise donation. If a child dies in circumstances where they can become a donor and they haven’t authorised donation (or ‘opted in’), then authorisation may be provided by a person with PRRs for the child (unless PRRs are held by a local authority). For a child under 12, authorisation may only be given by a person with PRRs.</p>

	<p>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 for adults (aged 16 and over). Changes in the Bill regarding children are largely consequential to some of the changes for adults but seek to uphold the principles of the UNCRC in advancing children’s rights.</p> <p>The proposed soft opt out system will mean that an adult can continue to register a decision to donate or not to donate. In cases where an adult 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. Children would be included in a certain category of people who would require explicit authorisation, rather than being subject to deemed authorisation. This explicit authorisation could come from themselves during their lifetime (for those aged 12 and over) or from a person with PRRs upon their death. Additionally, adults (aged 16 or over) who are resident in Scotland less than 12 months and adults without the capacity to understand deemed authorisation would also require explicit authorisation, either from themselves or a nearest relative.</p> <p>Those working in donation would be required to check with any potential donor's family members, or any other person who has indicated that they wish to provide information, about any views the potential donor held on donation. This is in order to give effect to the Bill’s overarching aim to give precedence to the views of the potential donor, 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.</p> <p>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.</p>
<p>Scope of the CRWIA</p>	<p>This assessment focuses on the impacts of the specific changes to authorisation, rather than the potential impacts on transplant recipients.</p> <p>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 and young people with experience of being looked after to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed. Additionally, focus groups with adults with learning difficulties were undertaken to understand what they thought about</p>

	<p>particular elements of the proposals and how changes could best be communicated to people, including young people, with learning difficulties.</p> <p>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, as well as with those with responsibility for paediatric donation.</p>
<p>Children and young people's views and experiences</p>	<p>In addition to the formal consultation, further in-depth qualitative research was carried out in conjunction with the Scottish Health Council with specific groups of people who would be impacted by the legislation. This included focus groups with young people and a focus group and small survey with care-experienced young people in order to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed.</p> <p>The young people without care experience were supportive of a soft opt out system of donation. They expressed a range of views about what the appropriate age would be, both for self-authorisation and deemed authorisation and overall both groups thought that 15-16 would be an appropriate age for deemed authorisation to start from. The young people thought it was very important for children and young people to learn about donation, to have discussions with their parents and to be able to register their wishes.</p> <p>The focus group and survey with care-experienced young people sought views on the move to an opt out system and also on the proposal to allow local authorities to decide whether to authorise donation for a child for whom they hold PRRs. The care-experienced young people had mixed feelings about donation in general and moving to a soft opt out system in particular, and there was concern that public awareness might not be sufficient for the system to work properly. The focus group also considered the age at which a person should be able to authorise donation and thought that 12-16 was too young.</p> <p>With regards to the question on local authorities being able to authorise donation, the care-experienced young people in the focus group had mixed views on who was most appropriate to make a decision or offer views 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. They were also asked if views should be sought from others to inform the donation decision and had mixed views on this point.</p> <p>All the young people had lots of ideas about how they should be informed about any changes to the donation system.</p>

	<p>Together, the Scottish Alliance for Children’s Rights responded to the consultation, highlighting the need for awareness raising amongst young people, parents/carers and medical staff about children’s rights in the soft opt out system. Together highlighted the need for children to be able to make their views known, to exercise their rights as they acquire the competence to do so and for information relating to children who register their wishes to be held securely with confidentiality. Together highlighted the need for the inclusion of Corporate Parenting roles in authorisation to be scrutinised through a full CRWIA to ensure any proposals are underpinned by the UNCRC.</p>
<p>Key Findings</p>	<p>There is scope for the legislation to impact on a number of the articles contained within the UNCRC. These include (but are not limited to):</p> <ul style="list-style-type: none"> • Article 3 - Best interests of the child • Article 12 - Respect for the views of the child • Article 13 - Freedom of expression • Article 16 - Right to privacy • Article 23 - Children with disabilities • Article 14 - Freedom of thought, belief and religion <p>Of the eight wellbeing indicators (Safe, Healthy, Achieving, Nurtured, Active, Respected, Responsible, Included - known by the acronym, SHANARRI), the legislation is relevant to:</p> <ul style="list-style-type: none"> • Respected <p>There is no direct evidence of the impact of opt out systems of donation on different age groups or children. The views of the young people who took part in the focus groups and survey have been a useful source of information to inform the development of the legislation and the plans for awareness raising campaigns and public information.</p> <p>The provisions in the Bill provide a balance between safeguarding and enabling children and young people’s rights. The opt out system includes a safeguard whereby children (under 16) will not be eligible for deemed authorisation and will instead require explicit authorisation, 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 and new provisions will enable them to make a declaration opting out of donation.</p> <p>A number of minor technical changes are also being made with regards to authorisation requirements to bring them in line with those for adults. Children aged 12 and over will continue to be able to record donation decisions on the Organ Donor Register and a Data Protection Impact Assessment has been carried out to ensure data is held securely with confidentiality.</p> <p>One of the Bill’s overarching aims is to give precedence to the views of the potential donor, which will mean in all circumstances, and for all</p>

people, it should be the views of the potential donor which determine whether donation goes ahead.

To ensure this is the case the Bill includes a requirement for those working in donation to check with any potential donor's family members about any views the potential donor held on donation. These discussions are usually led by a Specialist Nurse for Organ Donation or a Tissue Donor Coordinator, including those with specialist skills in paediatric donation, who are specially trained to discuss donation with families during such a difficult time and help them to reach a consensus view on donation and support the potential donor's decision where one has been made.

In order to optimise the potential for the child's views to be known and adhered to when authorisation is being considered by a person with PRRs, they will be required not only to take into account their own knowledge of the child's views but any relevant information from other people for example other family members or friends, and they must ultimately be satisfied that the child wasn't unwilling to become a donor.

As identified in the Equalities Impact Assessment (EQIA), the point at which death occurs is an important factor in decision making about donation for some people of particular faiths. The Bill includes specific provision about the particular circumstances of death which will mean that in all cases – whether a child has recorded a donation decision, or whether authorisation is being considered on their behalf, donation may only proceed where it is consistent with the child's views in this regard.

These changes are being introduced for all age groups which will increase the current protections for children, especially those aged under 12, for whom there is currently no requirement for a person authorising on their behalf to take into account any unwillingness to donate.

Young people aged 16 and over are classified as 'adults' in the legislation and will therefore be subject to deemed authorisation, apart from those who are resident in Scotland less than 12 months and adults without the capacity to understand deemed authorisation – these groups would require explicit authorisation. The legislation contains safeguards to prevent those adults who are subject to deemed authorisation, and do not wish to become a donor, from doing so, even if they haven't recorded an opt out decision. Family members or others will be able to advise of any objection to donation the potential donor held, meaning donation wouldn't proceed.

The Bill includes provision to enable a local authority, in the absence of a donation decision made by a child for whom it holds PRRs, to decide whether to authorise donation should the child die in circumstances where he or she could become a donor. In order to take account of varying personal circumstances, the Bill will require that, in deciding

	<p>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 particular impact for children aged under 12, as they are unable to authorise their own donation so currently, where the Local authority holds PRRs, donation could not proceed even if it was the child's stated wish. This issue was considered during the passage of the 2006 Act but did not proceed due to concerns about the appropriateness of local authorities in Scotland having this power. Given the 2006 Act has now been in place for over 10 years, and in line with the principles of the UNCRC it was considered appropriate to review this to offer this group of looked after children the same opportunity to donate should they wish to do so.</p> <p>The Bill also provides for the very rare circumstances whereby there is nobody with PRRs for a child, or they are incapacitated, such as following a family car crash. In these very unlikely circumstances authorisation could be given by another adult with a close relationship with the child, providing there is no knowledge the child would be unwilling to donate.</p> <p>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 reflect the changes and will be a useful resource to continue to raise awareness about donation, support children and young people to make informed decisions and educate them about how deemed authorisation would apply to those aged 16 and over.</p> <p>It will be important that the awareness raising campaign takes account of the needs of children and young people, as well as the needs of the other equalities groups as identified in the EQIA, such as those with disabilities and those who speak no, or little English. It will be important that young people are notified as they approach age 16 that they will become eligible for 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.</p>
<p>Conclusions and Recommendations</p>	<p>The Scottish Government has found that none of the proposals impinge upon articles of the UNCRC or the indicators of wellbeing (SHANARRI) and that the Bill will not have a negative impact on children and young people.</p>
<p>Monitoring and review</p>	<p>Responsible Official: Fern Morris</p> <p>Timetable: Throughout the parliamentary passage of the Bill and continuing through implementation of the provisions following Royal Assent.</p>

	<p>Methodology: The CRWIA consideration will continue during the passage of the Bill. For implementation, a process and impact evaluation will be carried out, as well as on-going monitoring by the Scottish Donation and Transplant Group, which provides advice to Scottish Ministers on all issues relating to organ and tissue donation and transplantation. Public attitudes and awareness are particularly important in an opt out system and monitoring will be informed by new data collections through representative surveys, which in turn will support the on-going development of public information. Existing routine data regarding donor and transplant numbers, as well as qualitative information, for example feedback from families involved in the process will continue to be used to inform training and improvement.</p>			
Bill - Clause	Aims of measure	Likely to impact on . . .	Compliance with UNCRC requirements	Contribution to wellbeing indicators
<p>A child aged 12 to 16 can make an opt out declaration which has legal effect.</p>	<p>To ensure that a child's decision not to be a donor has the same legal status as that of a decision to be a donor.</p>	<p>Children aged from 12 up to 16 who wish to opt out of donation.</p>	<p>This policy does not impinge on any of the UNCRC articles.</p> <p>We consider that it advances: Article 12 – Respect for the views of the child</p>	<p>The policy does not impinge on any of the indicators.</p> <p>We consider that it advances:</p> <p>Respected</p>
<p>Aligning methods for authorising or opting out of donation for a child with that for adults.</p>	<p>To bring into line with the approach for adults and broaden the methods by which a child can record a donation decision.</p>	<p>Children aged from 12 up to 16 who want to record a donation decision.</p>	<p>This policy does not impinge on any of the UNCRC articles.</p>	<p>The policy does not impinge on any of the indicators.</p>
<p>Duty to inquire about a child's most recent view on donation, including whether they would have been willing to donate in the specific circumstances of death.</p>	<p>To ensure that the child's most recent views on donation can be taken into account including views about donating after particular circumstances of death.</p>	<p>Children who are potential donors.</p>	<p>This policy does not impinge on any of the UNCRC articles.</p> <p>We consider that it advances: Article 12 –</p>	<p>The policy does not impinge on any of the indicators.</p> <p>We consider that it advances:</p> <p>Respected</p>

			Respect for the views of the child. Article 14 - Freedom of thought, belief and religion	
Authorisation cannot be given for a child if the child would have been unwilling to donate in the specific circumstances of death.	To ensure that particular concerns that some people have about donation proceeding after certain types of death are respected and that their views determine whether donation can be authorised.	Children who are potential donors and have views about donation proceeding after certain types of death, for example for religious reasons.	This policy does not impinge on any of the UNCRC articles. We consider that it advances: Article 12 – Respect for the views of the child Article 14 - Freedom of thought, belief and religion	The policy does not impinge on any of the indicators. We consider that it advances: Respected
Authorisation cannot be given for a child under 12 if the child would have been unwilling to donate.	To provide a protection for children under 12 by introducing the 'unwillingness test' when authorisation is being given on their behalf – as already provided for all other age groups.	Children under 12 who are potential donors.	This policy does not impinge on any of the UNCRC articles. We consider that it advances: Article 12 – Respect for the views of the child	We consider that it advances: Respected
A person authorising donation on behalf of a child must have regard to information from other people	To increase the potential for the child's views to influence whether	Children who are potential donors and have not recorded a	This policy does not impinge on any of the UNCRC	The policy does not impinge on any of the indicators.

about the child's views and be satisfied that the child was not unwilling to donate.	donation is authorised.	donation decision.	articles. We consider that it advances: Article 12 – Respect for the views of the child	We consider that it advances: Respected
A local authority which holds PRRs for a child can authorise donation, in consultation with others with a relationship with the child and taking into account the views of the child.	To enable a donation decision to be taken on behalf of a child who hasn't already recorded a decision by the local authority if it holds PRRs	Children up to the age of 16 who are potential donors and for whom a local authority holds PRRs.	This policy does not impinge on any of the UNCRC articles. We consider that it advances: Article 12 – Respect for the views of the child Article 3 – Best interests of the child	The policy does not impinge on any of the indicators. We consider that it advances: Respected
A person other than a person with PRRs can authorise donation for a child when there is nobody with PRRs.	To enable a donation decision to be taken on behalf of a child who hasn't already recorded a decision in the very rare circumstances that there is nobody with PRRs or they are incapacitated.	Children up to the age of 16 who are potential donors and there is nobody who holds PRRs for them or they are incapacitated.	This policy does not impinge on any of the UNCRC articles. We consider that it advances: Article 12 – Respect for the views of the child	The policy does not impinge on any of the indicators.
CRWIA Declaration				
CRWIA required			CRWIA not required	
Yes				

Authorisation	
Policy lead Fern Morris Policy Officer Health Protection Division	Date June 2018
Deputy Director or equivalent Gareth Brown Deputy Director Health Protection Division	Date June 2018



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