

Organ Donation (Isle of Man) Bill 2018

Overview

On the Island, approximately 12,600 island residents are registered on the UK NHS Organ Donor Register. Many people have made the generous gift of their organs and tissue to help someone else in the event of their death, but despite many people registering there is still a shortage of donors.

Why we are consulting

The proposed change is intended to help the system better reflect the position of the majority of people who would be happy to donate their organs and tissue when they die. It will also respect the decisions of those who do not wish to be donors.

Introduction from Martyn Perkins

In October I was given leave to introduce a Private Members Bill.

Following conversations with healthcare professionals, the family members of donors, transplant patients and members of the public I have brought forward draft legislation about introducing a 'presumed consent' system for organ donation for discussion.

The donation of organs and tissue after death helps to save many lives each year. One donor can transform the lives of up to nine other people.

Presumed consent is alternatively known as an 'opt-out' system. This means that unless the deceased has expressed a wish in life **not** to be an organ donor, then consent will be assumed.

The intention of the Bill is to increase the number of people willing to become an organ donor.

The aim of this draft legislation is to make sure people are aware they can opt in (either by registering or doing nothing) or opt out, making both decisions easier to record.

Introduction

The proposed change is intended to help the system better reflect the position of the majority of people who would be happy to donate their organs and tissue when they die. It will also respect the decisions of those who do not wish to be donors.

The consultation is considering consent for organ and tissue donation after death only. No changes are proposed to the current rules and processes regarding living donors.

This consultation seeks responses on what, if any, changes to the organ donation system we should make including proposals to:

- make it easier for people to register their decision on organ and tissue donation – this is to ensure decisions people make about organ donation are honoured after their death
- change the law so that people would be considered willing to be an organ donor unless they decide to opt out
- how family members should be involved in confirming decisions
- changes, exemptions and safeguards for certain groups of people under the new system

We also invite views on the potential impact on certain groups, for example, people who have protected characteristics in law such as disability, race, religion or belief.

Related Information

The IOM Government has plans for every patient to be able to **access their own medical records** <<https://www.gov.im/news/2017/may/10/digital-health-records-go-live-at-nobles-hospital/>> and complete a number of different services online. A link to the **UK NHS Organ Donor Register** <<https://www.organdonation.nhs.uk/>> will be included in the online service.

What is your name?

Name

What is your email address?

When you enter your email address you will automatically receive an acknowledgement email when you submit your response.

Email (Required)

Are you responding on behalf of an organisation?

Please select only one item

Yes No

If yes, please tell us which organisation

Are you resident in the Isle of Man?

Please select only one item

Yes No

If yes, please tell us the first three digits of your postcode

May we publish your response?

More information

- Publish in full – your first name and surname, organisation name, along with full answers **will** be published on the hub (your email will **not** be published)
- Publish anonymously – only your responses **will** be published on the hub (your name, organisation and email will **not** be published)
- Do not publish – **nothing will** be published publically on the hub (your response will only be part of a larger summary response document)

(Required)

Please select only one item

- Yes, you can publish my response in full
- Yes, you may publish my response anonymously
- No, please do not publish my response

Current organ donation consent

A person is considered a possible organ donor following their death only if they actively took steps to consent in their lifetime.

Currently on the Island, donation is more likely to take place if:

- a person has given their **express consent** for organ donation
 - by registering on the NHS Organ Donor Register or
 - by making their decision known to their family
- their family has **given consent on their behalf**

If the person's decision is **not known**, their family is approached for consent to proceed with a donation.

People who are happy to be organ donors, but who do not make their decision known, risk this decision not being honoured after their death.

Some people make the decision not to donate their organs after their death. For example, this may be because of religious or other beliefs.

Note that ticking the box on an IOM driving licence application does not currently automatically register you as a donor.

Organ donation in neighbouring jurisdictions

- The UK Government is considering a similar bill and ran a consultation during the first three months of 2018. This received over 11,000 responses and responses and feedback from this consultation are **not yet available** <<https://www.gov.uk/government/consultations/introducing-opt-out-consent-for-organ-and-tissue-donation-in-england>> .
- In Wales, an **opt-out system** <<http://organdonationwales.org/?lang=en>> was introduced in 2015. The latest evidence on this shows that awareness of and support for the system of organ donation in Wales is high among the public and NHS staff. Consent rates have also risen. However, analysis of routine data does not show any consistent change in deceased organ donations in Wales, and a longer period of monitoring is required to understand the impact of the change in the law.
- The Scottish Government consulted on increasing organ and tissue donation, including proposals for a potential soft opt out system of donation from 7 December 2016 to 14 March 2017. Feedback on this consultation is available on the Scottish Government's **consultation webpages** <<https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/>> .

1 Are you a registered organ donor?

Please select only one item

- Yes No Don't know No - but I have thought about registering
 No - I don't know how to register

2 Have you had experience of any part of the process of organ donation?

For example, have you or a family member received or donated an organ.

Please tell us of any previous experience of organ donation

3 Have you ever discussed organ donation with family members / other next of kin?

The Isle of Man Government encourages people to sign up as organ donors on the **NHS Organ Donor Register** <<https://www.organdonation.nhs.uk/>> and to tell their families that they want to donate.

Please select only one item

Yes No

Download the consultation document - Organ Donation Bill 2018 <user_uploads/organ-donation-bill-2018.pdf>

Duty to promote transplantation

The Department of Health and Social Care's duties in relation to promoting transplantation are outlined in Part 2 (6) of the **Organ Donation Bill 2018** <user_uploads/organdonationbill2018_v02.pdf> .

Part 2: Promotion of transplantation

(6) Duty of the department to promote transplantation

W2013/5/2

(1) The Department must —

- a. **promote transplantation** as a means of improving the health of the people of the Island
- b. provide information and **increase awareness** about transplantation
- c. inform the public of the circumstances in which **consent** to transplantation activities is **deemed to be given** in the absence of express consent and
- d. ensure that the **resources available** to the Department include the specialist skills and competencies required for the purposes of this Act

(2) The duty under subsection (1) includes in particular an obligation on the Department, **at least once every 12 months**, to promote a campaign for the purpose of informing the public in the Island about the circumstances in which consent to transplantation activities is deemed to be given in the absence of express consent.

(3) The Department must, for the **first five years** after this section comes into force, **report annually** to Tynwald on the steps taken to fulfil their duty under subsection (1).

4 Do you have any ideas or suggestions about how the Isle of Man Government could encourage more people to register as organ donors?

Please provide ideas below

Download the consultation document - Organ Donation Bill 2018 [<user_uploads/organ-donation-bill-2018.pdf>](user_uploads/organ-donation-bill-2018.pdf)

Consent

Currently on the Island people must actively consent to being an organ donor and choose to opt in, although donations can currently occur on patients for whom no data is held, where the family consent to donation.

Our proposal

Presumed consent

Under the proposed system a person will be considered to have consented to organ and tissue donation after death **unless** they opt out. This makes it important that people are aware of the changes and can simply and easily express their decision.

Changing the system would **require** people to **actively register** their decision to **opt out**.

A move to 'presumed consent' would require:

- a solid and well-understood legal framework
- changes to clinical practice and professional ethics, including the referrals process between clinical teams and specialist nurses for organ donation

Consultation and engagement

During this consultation period, we'll be:

- reviewing information from other jurisdictions and
- engaging closely with clinical leaders to understand the implications of potential changes to practice and guidelines

A new system of consent should make it easier to record a decision, to change that decision if necessary, keeping your wishes up to date.

Donation suitability testing

All potential donors would be subject to suitability testing, as at present, so a desire to donate does not guarantee a donation can occur.

5 Do you think people should have more ways to record a decision about organ and tissue donation?

Select all that apply.

Please select all that apply

The NHS Organ Donor Register online Your IOM medical records online

When registering with a GP

Yes – there should be a number of ways to record a decision

No – you should only be able to record your decision directly onto the NHS Organ Donor Register online or on the phone

Other

If other, please specify

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Consent of children

Part 3 (10) of the **Organ Donation Bill** <[user_uploads/organdonationbill2018_v02.pdf](#)> outlines the consent for organ transplantation of children.

Organs donated in the Isle of Man would be used in transplantation surgery in England. In England, consent transitions from parental / guardian consent to the individual's consent on the potential donor's 18th birthday.

Part 3 (10) Consent: Children

Part 3: Lawful transplantation activities

Section 10 Consent: Children

W2013/5/6

(1) This section makes provision about consent for the purposes of Section 3 in relation to a transplantation activity involving the body, or relevant material from the body, of a person who is a child or has died a child.

(2) In the case of a person who is a child or has died a child express consent is required.

(3) For each case mentioned in the first column of Table 3 the meaning of express consent in relation to an activity is as provided in the second column of the table —

Table 3

Case	Meaning of express consent
1. The child is alive and case 2 does not apply	The child's consent.
2. The child is alive, no decision of the child to consent, or not to consent, to the activity is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.	Consent of a person who has parental responsibility for the child.
3. The child has died and a decision of the child to consent, or not to consent, to the activity was in force immediately before death.	The child's consent.
4. The child has died, case 3 does not apply, the child has appointed a person or persons to deal with the issue of consent in	Consent given by the person or persons appointed.

<p>relation to the activity and someone is able to give consent under the appointment.</p>	
<p>5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.</p>
<p>6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.</p>

(4) In this section a decision or appointment made by a child is only valid if the child was competent to deal with the issue of consent when it was made.

(5) In this section a reference to the appointment of a person or persons to deal with the issue of consent is a reference to an appointment under section 12.

(6) This section does not apply to consent for a transplantation activity that involves removal of excluded relevant material (for provision in relation to which see section 11).

6 For the purposes of organ donation do you think that the cut-off date for being regarded as a child should be 16 or 18?

Please select only one item

16 18

Please tell us why you have chose this age

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Consent: adult exceptions

Part 3 (9) of the **Organ Donation Bill** <[user_uploads/organdonationbill2018_v02.pdf](#)> outlines organ transplantation consent of excepted adults.

An **excepted adult** means –

- a. an adult who has died and who had not been ordinarily resident in the Island for a period of at least 12 months immediately before dying **or**
- b. an adult who has died and who for a significant period before dying lacked capacity to understand the notion that consent to transplantation activities can be deemed to be given

A significant period means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.

Table 2 – Excepted adults cases and consent

Case	Meaning of express consent
1. A decision of the excepted adult to consent, or not to consent, to the activity was in force immediately before death	The excepted adult's consent.
2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity and someone is able to give consent under the appointment	Consent given by the person or persons appointed.
3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.
4. None of cases 1, 2 or 3 applies in relation to the excepted adult	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.

Changing to an opt-out system of consent

What your decision means – definitions

- **Opt out** – you can choose not to be an organ donor after your death
- **Opt in** – you can choose to make your decision known that you wish to be an organ donor after death, streamlining the process to donate all or some organs and tissues
- **Do nothing** – would mean you support becoming a donor – this consultation asks how 'presumed consent' should work

7 If the law changes, would this affect your decision about organ donation?

Please select only one item

- No – it would make no difference
- Yes – it would make me want to become an organ donor after my death
- Yes – it would make me want to opt out of being an organ donor after my death

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Equalities

Moving to an opt-out system of consent could affect people from different backgrounds in different ways.

There is **less likely** to be an impact on those with the protected characteristics of:

- gender reassignment
- pregnancy and maternity
- sexual orientation

Age and **disability** are important factors when considering how consent is obtained.

Where a person is not able to make an informed decision on the basis of disability, exceptions could be introduced on the basis of age and mental capacity to ensure that these individuals are not negatively impacted.

The proposed changes could have a **more significant impact** in relation to **race** and **faith**.

Equalities Act Isle of Man

Following the announcement of Royal Assent, on 18 July 2017 the **Equality Act 2017** <https://www.legislation.gov.uk/cms/images/LEGISLATION/PRINCIPAL/2017/2017-0005/EqualityAct2017_2.pdf> is being phased in, with all of the provisions expected to come into operation by January 2020.

For further information on implementation dates see the **Equality Act** <<http://www.gov.im/equalityact>> webpages.

8 Do you think this change could have any particular impact on people from some religious groups or ethnic backgrounds?

If the law changes, people would be considered willing to be an organ donor unless they have opted out.

Please select only one item

Yes No Don't know

Do you think the change could have any impact on people depending on their age or any particular condition they may have that may affect their mental capacity to make an informed decision to donate. If yes what could be done to address that impact.

Download the consultation document - Organ Donation Bill 2018 [<user_uploads/organ-donation-bill-2018.pdf>](user_uploads/organ-donation-bill-2018.pdf)

Family involvement in decisions to donate

Provision with respect to consent

Changing the law on organ donation consent would have a direct impact on families.

There are different options for settling the role of family members in decisions on organ and tissue donation consent.

These are:

- no role for families in consent
- an expectation that family members are consulted, to understand what their relative's decision was
- a formal ability to overrule consent

Family consent

Lack of family consent is an important factor that determines whether potential donations go ahead. Decisions on organ donation consent take place at a highly emotional time following the death of a relative.

Where a potential donor has not made their decision known, it can be difficult for relatives to decide on their behalf. This can put pressure on family members or close friends.

Families may not support organ donation because they:

- are not sure what their loved one would have wanted
- knew their relative did not want to be a donor.
- believe their relative 'had been through enough'
- are concerned that the time involved in the donation process increases distress

Family members are approached, if organ or tissue donation becomes a possibility, to seek information about a number of issues, including:

- whether they knew the decision their relative had made regarding organ donation
- whether the family had reason to believe that their relative had changed their mind following recording a decision on the NHS Organ Donor Register
- medical and lifestyle history to ensure that organs would be safe to transplant

Family members making the final decision regarding organ donation

At present, there is no legal requirement to consult with the family of a deceased relative where appropriate consent is in place at the time of death.

In practice, families or a nominated individual will be consulted to confirm a decision even where a donor has expressly recorded their wish to become an organ donor and 'opted in' under the current system of consent to organ donation.

Part 5 (20) Provision with respect to consent

Part 5 (Section 20) of the **Organ Donation Bill** <[user_uploads/organdonationbill2018_v02.pdf](#)> outlines the standards for obtaining consent from family members

20 Provision with respect to consent

(1) The duty under section 19(3) has effect, in particular, to require the Department to lay down the standards expected in relation to the obtaining of consent where consent falls by virtue of a provision listed in subsection (2) to be obtained from a person in a qualifying relationship.

(2) Those provisions are section 8(3), 9(4), 10(3) and 11.

(3) Subject to subsection (4), the standards required to be laid down by subsection (1) must include provision to the effect set out in subsections (5) to (9).

(4) The standards required to be laid down by subsection (1) may include provision to different effect in relation to cases which appear to the Department to be exceptional.

(5) The qualifying relationships for the purpose of a provision listed in subsection (2) should be ranked in the following order—

- a. spouse, civil partner or partner
- b. parent or child
- c. brother or sister
- d. grandparent or grandchild
- e. child of a person falling within paragraph (c)
- f. stepfather or stepmother
- g. half-brother or half-sister
- h. friend of longstanding

(6) Relationships in the same paragraph of subsection (5) are to be accorded equal ranking.

(7) Consent should be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subsections (5) and (6).

(8) If the relationship of each of two or more persons to the person concerned is accorded equal highest ranking in accordance with subsections (5) and (6), it is sufficient to obtain the consent of any of them.

(9) In applying the principles set out above, a person's relationship shall be left out of account if—

- a. the person does not wish to deal with the issue of consent,
- b. the person is not able to deal with that issue, or
- c. having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with the person within the time available if consent in relation to

the activity is to be acted on.

(10) The duty under section 19(3) also has effect, in particular, to require the Department to give practical guidance on the circumstances in which consent is deemed under section 4 (consent of adults that are not excepted) of the Human Transplantation (Wales) Act 2013.

(11) In giving practical guidance on the circumstances in which consent is deemed the authority must, in particular, give guidance on how a relative or friend of long standing of the deceased can object on the basis of the deceased's wishes.

(12) After carrying out such public consultation as it thinks appropriate, the Department may by order amend subsection (5).

Tynwald procedure for an order under this subsection – approval required.

9 If the law changes and someone has died, and they have not opted out of organ donation, should their family be able to make the final decision?

Please select only one item

Always – if someone has not opted out, their family should always be asked to make the final decision

Sometimes – there are some circumstances where someone's family should make the final decision

Never – if someone has not opted out, donation should always go ahead

Other

If other, please specify

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Family members overruling decisions regarding organ donation

Provision with respect to consent

Organ donation always occurs at a time of great distress for the family, after hearing that a loved one has died or is expected to die. Many people therefore find it very difficult to be asked for a decision at this time.

In many cases, families find it much easier to support donation if they know the decision of their loved one. Many of families agree to donation if they know it was what their loved one wanted to do after their death. However, some families do not support a decision to consent as recorded on the NHS Organ Donor Register. As a result, the donation does not proceed.

10 Do you think someone's family should be able to decide if their organs are donated, if it is different to the decision they made when they were alive?

Please select only one item

No – someone's family should never be able to make a different decision about organ donation

Sometimes – there are some circumstances where someone's family should be able to make a different decision

Yes – someone's family should always make the final decision, even if it is different to what the person decided

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Exceptions and safeguards in an opt-out system

Activities involving material from adults who lack capacity to consent

Following a move to a deemed consent system of organ donation, there are some groups of people where existing opt-in consent should continue to be obtained, from the individual either themselves or a parent, guardian or family member:

- **living children** who are competent to make decisions can give their own consent
- where a child is **not competent** (or has not decided), appropriate consent can be given by a person with parental responsibility for that child – if there is no such person, a person in a qualifying relationship can decide
- **living adults** must actively give their own consent on what happens to their body after death

A person in a qualifying relationship could include a:

- spouse / civil partner
- partner
- parent
- brother / sister
- grandparent
- grandchild
- child of a brother or sister
- stepfather / stepmother
- half-brother / half-sister
- friend of long standing

There are exceptions that include people for whom there may be concerns about their ability to make a decision and fully understand the consequences of it.

Exceptions

Exceptions include:

Children

Although the circumstances will vary, consent to medical treatment is often obtained on behalf of a child from a parent or guardian where the patient is under 16.

However, it might be appropriate to exclude children aged under 18 from an opt-out system of consent for organ and tissue donation after death.

This would mean that, unless a child has capacity and has recorded their decision, the person with parental responsibility would continue to give consent for organ donation to occur.

People who lack capacity

This includes, for example, an adult with advanced dementia or severe learning difficulties who is unlikely to be able to understand the consequences of not opting out. It is important that a lack of capacity should not be assumed, and that support is provided to help someone to make an informed decision where possible and appropriate.

Part 3 (13) Adults who lack capacity to consent

Part 3 Lawful transplantation activities

Section 13 Activities involving adults who lack capacity to consent

W2013/5/9

(1) This section applies where —

- a. a transplantation activity within section 7(2)(c) or (d) (storage or use of relevant material which has come from a human body) done in the Island involves relevant material from the body of a person (P) who
 - (i) is an adult, and
 - (ii) lacks capacity to consent to the activity, and
- b. no decision of P's to consent, or not to consent, to the activity is in force.

(2) P's consent to the activity is to be deemed if the activity is done in circumstances of a kind specified by regulations made by the Department.

11 If the Isle of Man moves to an opt-out system, should any of the following groups NOT be included in presumed consent?

Please select only one item

- Children under 16 years old Children under 18 years old
- People who lack capacity to consent
- Visitors to the Island unless registered elsewhere
- People living on the Island for less than 12 months unless registered elsewhere
- No – they should all be included

Are there any other groups you think should not be included? Please tell us which groups and why you think this.

Download the consultation document - Organ Donation Bill 2018 <user_uploads/organ-donation-bill-2018.pdf>

Codes of practice

The **Organ Donation Bill** <user_uploads/organdonationbill2018_v02.pdf> creates a duty on the department to produce and keep under review **Codes of Practice** <user_uploads/part-5--19--codes-of-practice.pdf> for organ donation.

This covers practical guidance and standards.

Codes of practice

Part 5 – General Provisions

Section 19 – Codes of Practice

P2004/30/26

- (1) The Department must prepare and issue codes of practice for the purpose of –
- a. giving practical guidance to persons carrying on activities to which this Act applies, and
 - b. laying down the standards expected in relation to the carrying-on of such activities.
- (2) The Department must deal under subsection (1) with the following matters –
- a. the carrying-out of anatomical examinations
 - b. the definition of death for the purposes of this Act
 - c. communication with the family of the deceased in relation to the making of a post-mortem examination
 - d. the making of post-mortem examinations
 - e. communication with the family of the deceased in relation to the removal from the body of the deceased, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains
 - f. the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains
 - g. the storage for use for a scheduled purpose, and the use for such a purpose, of –
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body
 - h. the disposal of relevant material which has come from a human body
- (3) In dealing under subsection (1) with the matters mentioned in subsection (2)(f) and (g), the Department must, in particular, deal with consent.
- (4) The Department must –
- a. keep any code of practice under this section under review, and
 - b. prepare a revised code of practice when appropriate.
- (5) Before preparing a code of practice under this section, the Department must consult such persons as it considers appropriate,
- (6) The Department must publish a code of practice issued under this section in such way as, in its opinion, is likely to bring it to the attention of those interested.

(7) A code of practice issued under this section shall come into operation on such day as may be appointed by directions.

(8) Codes of practice under this section –

- a. may make different provision for different cases; and
- b. must be laid before Tynwald.

12 Do you agree that Section 19 covers the topics that should be included in this code?

Please select only one item

Yes No

Please tell us if you think there is anything missing.

Download the consultation document - Organ Donation Bill 2018 <[user_uploads/organ-donation-bill-2018.pdf](#)>

Your opinions and final thoughts

Please tell us about any opinions or evidence you have about opting out of organ donation.

For example

- whether an opt-out system would change the organ donation consent rate
- whether higher consent rates increase the number of transplants
- whether implementing an opt-out policy is a good use of health system resources

13 Please tell us about any opinions or evidence you have about opting out of organ donation.

Do you have any final comments?

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