Department of Health & Social Care

Organs and tissues to be excluded from the new system of organ and tissue donation in England (known as “opt-out” or “deemed consent”)

Published 29 April 2019

Consultation on the Draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2019

Contents

Introduction

The Government recently passed the Organ Donation (Deemed Consent) Act 2019[1], a new law to change the rules for organ and tissue donation in England from 2020. The law introduced a system commonly called "opt-out" or "deemed consent".

From 2020, everyone in England over the age of 18 will be considered to be in favour of donating their organs and tissues after death unless they have said they don't want to donate their organs (they have "opted out"), have appointed someone to decide for them after death, or are in an excluded group.

When the law was debated in Parliament, the Government agreed it would only apply to routine transplants and that novel and/or rare transplants would be excluded.

The Government is proposing that novel or rare transplants will still require express consent. This means you or someone representing you must explicitly give permission for these organs or tissues to be donated. We have included the list of organs and tissues that the Government would exclude in this consultation.

While the Government does not anticipate changing the list of excluded transplants in the near future, we have set out how the list would change on page 10.

This consultation is to ask you if the Government is excluding the right organs and tissues. We would like you to answer five questions about what you think should happen.

Annex A summarises what will change and what will stay the same. Whatever the outcome of this consultation, you will still be able to use the Organ Donor Register (ODR) to opt in or out of organ donation. If you opt in, you will still be able to say which organs and tissues you do or do not want to donate.

Annex B sets out the list of common organs and tissues which the Government intends will be donated under deemed consent.

[1] http://www.legislation.gov.uk/ukpga/2019/7/enacted

Definitions

- Opt-out or deemed consent: the new consent arrangements that the Government is introducing mean that all adults over 18 are considered potential organ and tissue donors, unless they make a decision that they do not want to be a donor, they have appointed a representative to make a decision on their behalf after death, or are in an excluded group. The excluded groups are: people who lack mental capacity to understand deemed consent for a significant period before their death, children under 18, and people ordinarily resident in England for less than 12 months immediately before their death.

- Express consent: for the purposes of this document, express consent means that you, your nominated representative, or your family or close friends, can give or have explicitly given permission to donate.

- Tissues: a group or layer of cells that perform specific functions. For example, skin tissue is a group of skin cells.

- Organs: a relatively independent part of the body that carries out one or more special functions. Examples of organs include the kidneys, heart, lungs, and liver. In some cases, where the whole organ cannot be used, part of the organ may be transplanted instead.

- Novel and rare transplants: transplants that are new and are usually at a research or practical evaluation stage, or have gone through research and service evaluation stages, but are still rare and unusual. An example of a novel transplant would be face transplantation. An example of a rare transplant would be limb transplantation. These forms of transplant are unusual, and people might not expect them to be included in opt-out for organ and tissue donation.

- Routine transplants: common and well-established transplants that are offered on the NHS. It is intended that these will be included in opt-out and are listed at Annex B.

- Relevant material: parts of the human body, other than gametes, which consist of or include human cells. In the Human Tissue Act 2004, references to relevant material from a human body exclude embryos outside the human body, or hair and nail from the body of a living person.

- Permitted material: relevant material to which deemed consent applies and therefore would be covered in opt-out.

- Advanced Therapy Medicinal Products (ATMPs): tissues and cells from deceased donors can be used to manufacture ATMPs. ATMPs are classified as medicines for

human use and are based on manipulation of genes, tissues or cells. They often use human cells and tissues as starting materials. The majority use living donors and the patient's own cells but a small number use material from deceased donors. ATMPs are also a type of novel transplant.

- Code of Practice: practical guidance for healthcare professionals involved in organ and tissue donation, retrieval, and transplantation. The Human Tissue Authority is currently drafting a revised Code on how the new opt-out system will work in practice and will hold a public consultation from May 2019.

About this consultation

The new system of consent for organ and tissue donation - known as 'opt-out' or "deemed consent" - will be introduced in England from 2020. This means that adults in England will be considered to have given their consent for organ donation except in the following situations:

- they made a decision to not donate their organs and/or tissues
- they have appointed a representative to make a decision on their behalf after death
- they are in one of the excluded groups (under the age of 18; ordinarily resident in England for less than 12 months before their death; lack mental capacity for a significant period before their death).

The family of the deceased will always be consulted first and they will still be able to provide information on their loved one's wishes. If they have information that their loved one would not have wanted to donate their organs, organ donation will not go ahead.

The Government is proposing that deemed consent will only apply to organs and tissues considered to be 'routine' transplants. The policy intent has always been to exclude novel and rare transplants, including situations in which cells from a retrieved organ would be used to create an Advanced Therapy Medicinal Product (ATMP). Use of organs and tissues for non-transplantation purposes, such as research, is outside the scope of deemed consent.

Therefore, it is intended that only the following routine transplants of organs and tissues are included in opt-out:

- heart, transplanted either as a whole organ or for heart valves
- lung(s)
- liver, transplanted either as an organ or for liver cells (called "hepatocytes"), unless they are used for an ATMP
- kidneys
- pancreas, transplanted either as a whole organ or for pancreatic cells which produce insulin (called "islets"), unless used for an ATMP
- intestinal organs (small bowel, stomach, abdominal wall, colon, spleen)
- eye

- nervous tissue
- arteries/veins/blood vessels
- bone
- muscle
- tendon
- skin
- rectus fascia (tissue that encases abdominal muscles)

These transplants are very common. However, as only 1% of people die in circumstances that would allow donation, there are a lot of people on the UK waiting list for such a transplant. For example, last year, 3,500 people had their sight restored through receiving donated corneas (part of the eye) but we need an additional 700 eye donations per year to meet clinical need.

The Government is proposing that for rare transplants (e.g. limb transplants) or novel transplants (e.g. face transplants), the current practice of having express consent in place for the transplant to take place should continue. This is because the public may not expect rare or novel transplants to be included in opt-out.

Currently, if someone has registered on the Organ Donor Register (ODR), they can specify which routine organs they want or do not want to donate. For example, it is possible to say they do not want to donate their corneas. Under the new system, people will still be able to use the ODR in the same way, to opt in or out of donating some or all of their organs and tissues.

In cases where organ or tissue donation is a possibility, the family (or someone else, such as a long-standing friend of the deceased or nominated representative) will discuss the donation process with the specialist nurse and the wishes of the deceased, including which organs/tissues might be donated. Families will be given the opportunity to ask any questions they wish and to receive answers before they make a decision.

The purpose of this consultation is to seek the views of the public on what organs and tissues for transplantation they would not expect to be included in opt-out, because those kinds of transplants are novel and/or rare.

The powers to make the relevant regulations and consult are set out in the Human Tissue Act 2004 as amended by the Organ Donation (Deemed Consent) Act 2019, which became

an Act of Parliament on 15 March 2019. These proposed regulations will apply to England only.

Deemed consent will not apply to organs and tissues used for research. The practice of approaching families, close friends, or a nominated representative for express consent for organs and tissues to be used for research will continue. The family/close friends/representative can also confirm whether they want to apply any restrictions to the use of organs and tissue for research, for example, genetic research, animal research, or for commercial purposes. Research is therefore outside the scope of this consultation.

Annex A provides a snapshot of the proposed new system.

Annex B sets out the list of common organs and tissues which the Government intends will be donated under deemed consent.

Particular questions are asked throughout the document to guide the preparation of the Government Response to the consultation.

The Government has considered it appropriate to consult the public in this instance, as a new system of consent to organ and tissue donation is introduced. It is also the first time that the public has been consulted on the issue of novel/rare transplants. If the Government considers it necessary, there will be further public consultation on future changes to the regulations as and when such changes are contemplated.

The consultation will run from 29 April 2019 until 22 July 2019.

Background to the consultation

In October 2017, the Prime Minister made a bold commitment to change the current system of organ and tissue donation in England to help more people receive a much-needed organ and tissue transplant. Currently in England, over 5,100 people are waiting for a transplant. By the time a transplant is found, some people have become too ill to receive one. In England last year alone, 643 people were removed from the waiting list for this reason and a further 339 died while on the waiting list.

Although 80% of people say they would be happy to donate their organs after their death, only 37% are registered as donors. To increase the number of donors, the Government changed the law in line with what the majority of people want to do.

As the Government set out in the original consultation document on introducing opt-out in England and the subsequent Government Response, under the new system which is due to come into effect from spring 2020, if someone has died and they have not made a decision about organ and tissue donation before their death, unless they have nominated someone else to make a decision for them after death or are in one of the excluded groups, the default position will be that consent to donate will be considered to be in place. This new system of consent is known as "opt-out' or "deemed consent".

The Organ Donation (Deemed Consent) Act 2019 sets out the key principles for the new system. Children below the age of 18, people who lacked mental capacity to understand deemed consent for a significant period before their death, and people living in England for less than 12 months immediately before their death, will be excluded. Under the new system which Government will bring into force in spring 2020, after a 12-month communication campaign, the family will continue to be at the heart of decisions on organ donation for the deceased.

The Human Tissue Authority (HTA) has started developing a revised Code of Practice for the new system, for healthcare professionals, and will be formally consulting from May 2019. It will also publish a guide for the public.

The implementation of the Code will be supplemented by updated training and medical protocols for healthcare professionals led by NHS Blood and Transplant (NHSBT).

Intention of proposed regulations

Novel and rare types of transplants

Medical science can advance rapidly, making new procedures and types of transplants possible. However, it can take many years for a new transplantation procedure to become standard practice. This is because of the need for careful evaluation at each stage of its development to ensure that it is safe, effective, ethical for patients, and meets the needs of the population.

Before becoming standard practice, new transplants must go through two assessment stages: research and service evaluation.

Research will establish if a new form of transplantation is possible, safe, and effective. NHS Blood and Transplant (NHSBT) and NHS England will then carry out a service evaluation to assess whether the new transplant could and should be offered on the NHS. They will look at safety, effectiveness, impact, and practical issues, such as logistics and protocols.

Following the research and service evaluation stages, which can take several years, NHSBT's Research, Innovation, and Novel Technologies Advisory Group, made up of a number of experts and lay members, reviews all the evidence and makes a recommendation to NHSBT and NHS commissioners on whether to commission the procedure. If agreed by the NHS, the transplant can become standard practice and be commissioned as a service.

Several novel and/or rare transplants are currently being developed in the UK, such as uterine (womb) and face transplants. Limb transplants are already offered in Leeds General Infirmary for patients from across the UK, but this is a very rare form of transplant.

Advanced Therapy Medicinal Products, (ATMPs), are another form of novel transplant. ATMPs are classified as medicines for human use and are based on manipulating genes, tissues or cells. They often use human cells and tissues as starting materials. For example, an ATMP can treat knee damage by taking cartilage cells from a living patient, growing and modifying them in the lab, and then re-injecting them into the patient's knee. The modified cells can then repair the damage and heal the knee. The material for ATMPs sometimes comes from deceased donors.

Future development of novel transplants

There are several transplant procedures currently undertaken in other countries, which may be taken forward in the UK at some point in the future. Examples include penis and trachea (windpipe) transplantation.

Other types of novel transplants at research stage include cell therapies (e.g. using stem cells to repair or grow organs). These are still some years away from being successful.

What is Government's proposed approach?

Annex B sets out the list of common organs and tissues which the Government intends will be donated under deemed consent.

For rare and novel types of transplants, the Government intends that express consent will continue to be required from family or a close friend. It is also possible, but unlikely, that someone could give express consent to this before dying.

The Government would like to see further medical advances, although it recognises that this must be balanced with the rights of the individual and their family.

The policy intent of the draft regulations is to ensure that under deemed consent, consent for novel and rare transplants will continue to be expressed by family or close friends. However, the Government believes that the public needs to have an opportunity to give their views.

How would novel and rare transplants be removed from the excluded list?

If a novel transplant became standard practice and there was high demand for transplants of that organ or tissue, the Government would consider removing it from the list of organs and tissues excluded from opt-out. The Government does not expect this to happen in the near future. Before doing so, the Government would consult with NHSBT, NHS England and clinicians, and any other relevant clinical stakeholders. If the Government decided to go ahead, it would need to lay regulations in Parliament for debate and approval to make the change and, if approval was granted, it would issue a Written Ministerial Statement explaining why the change has been made and the impact it will have.

What will happen next?

Following the outcome of the consultation on the draft regulations, the Government will consider the responses and will issue a formal response in the form of a Command Paper, with a Written Ministerial Statement. The revised regulations will be laid in Parliament for debate and approval by both Houses before opt-out comes into effect in 2020. Ministers will be able to address any issues raised through the consultation. A Written Ministerial Statement will be issued after parliamentary approval, to highlight any impact on donation choices.

Impact Assessment

The Government published an Impact Assessment for the introduction of opt-out. No Impact Assessment has been produced for the draft regulations as they intend to maintain the current regime, where the express permission of the donor or their family will continue to be required for a novel or rare transplant to proceed. Therefore, no impact is foreseen on the private or voluntary sectors.

Consultation questions

The draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2019 set out the proposed list of organs and tissues for which someone will need to give express consent for these to be transplanted.

These are organs and tissues for which transplantation is considered novel and/or rare, therefore the public might not expect them to be included in opt-out. As a result, there may be a public expectation that someone's consent should not be deemed and, instead, express consent should be given for these novel and rare transplants to go ahead.

Question 1: Do you believe that the regulations as drafted are clear and comprehensive?

Yes – I understand what transplants will be excluded from opt-out.

No – I do not understand what transplants will be excluded from opt-out.

Question 2: Parts of the human body to be excluded from opt-out

In paragraph 2 of section 2 of the regulation, the Government proposes that the list of transplants below should be excluded from opt-out and therefore express consent will need to be given for such transplants to go ahead.

Do you agree with the Government's proposed list of excluded transplants below?

Please tick which of the following should be excluded from opt-out and instead express consent should be required for their removal:

- Tick here – if all of the below should be excluded from opt-out and express consent would be required for their transplant;
- brain
- spinal cord
- face
- nose
- mouth
- trachea (windpipe)
- arm
- upper arm
- forearm
- hand
- finger
- leg
- thigh
- lower leg
- foot

- toe
- ovary
- uterus
- penis
- testicle
- foetus
- placenta
- umbilical cord
- embryo (inside the body)

Question 3 – Tissues to be excluded if they are part of a novel and/or rare transplant ("excluded relevant material")

In paragraph 3 of section 2 of the regulation, the Government proposes that the following tissues, which would normally be included in opt-out, would require express consent if they are used for a novel and/or rare transplant.

This means that, under opt-out, arteries, for example, would be used for a liver transplant (which is a routine transplant), without the need for express consent from the deceased or their family. However, if arteries were needed for a novel or rare transplant, for example, a leg transplant, express consent would be required for using the arteries.

Please tick which of the following should be excluded from opt-out if they are part of a rare or novel transplant:

- Tick here – if all of the below should be excluded from opt-out and express consent would be required for their transplant
- eye
- nervous tissue
- artery/vein
- bone
- muscle

Organs and tissues to be excluded from the new system of organ and tissue donation in England (known as "deemed consent" or "opt-out")

- tendon
- skin

Question 4 – Specific tissues to exclude if they are for use in an Advanced Therapy Medicinal Product (ATMP)

Please tick which of the following should be excluded from opt-out if they are retrieved for use in an Advanced Therapy Medicinal Product:

- Tick here – if all of the below should be excluded from opt-out and express consent would be required for their transplant
- limbal stem cells (eye cells that allow the cornea to regenerate)
- liver cells
- pancreatic cells

Question 5 - Any other comments on the regulations not covered in these questions (please limit your comments on the proposed regulations rather than on opt-out on which the Government has consulted on previously).

The draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2019

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 3(9) and 52(1) of the Human Tissue Act 2004([2]).

In accordance with section 52(10)([3]) of that Act, the Secretary of State has consulted with such persons as the Secretary of State considers appropriate.

[In accordance with section 52(4) of that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.]

Citation, commencement, extent and application

1. —(1) These Regulations may be cited as the Human Tissue (Permitted Material: Exceptions) (England) Regulations 20XX and come into force [28 days after the day on which they are made].

(2) These Regulations extend to England and Wales only.

(3) These Regulations apply in relation to activities done in England for the purposes of transplantation([4]).

Relevant material that is not permitted material

2.—(1) Paragraphs (2), (3) and (4) specify types of relevant material([5]) that is not permitted material for the purposes of the definition of "permitted material" in section 3(9) ("Appropriate consent": adults) of the Human Tissue Act 2004.

(2) This paragraph specifies as types of relevant material the whole or any part of the following—
(a) brain;
(b) spinal cord;
(c) face;
(d) nose;
(e) mouth;
(f) trachea;
(g) arm;

([2]) 2004 c. 30 ("the 2004 Act"); subsection (9) was inserted into section 3 by section 1(5) of the Organ Donation (Deemed Consent) Act 2019 (c. 7).
([3]) Section 52(10) was amended, so far as relevant, by section 2(7) of the Organ Donation (Deemed Consent) Act 2019.
([4]) *See* section 54(3) of the 2004 Act as to references to transplantation in the Act.
([5]) *See* section 53 of the 2004 Act for the meaning of "relevant material".

(h) upper arm;
(i) forearm;
(j) hand;
(k) finger;
(l) leg;
(m) thigh;
(n) lower leg;
(o) foot;
(p) toe;
(q) ovary;
(r) uterus;
(s) penis;
(t) testicle;
(u) foetus;
(v) placenta;
(w) umbilical cord;
(x) embryo (inside the body)([6]).

(3) The whole or any part of the following are types of relevant material, only in so far as it is a composite part of any of the types of relevant material specified in paragraph (2)—

(a) eye;
(b) nervous tissue;
(c) artery;
(d) bone;
(e) muscle;
(f) tendon;
(g) skin.

(4) The following cells are types of relevant material, only in so far as all or part of the cells are for use in, or as, an advanced therapy medicinal product—

(a) limbal stem cells;
(b) liver cells;
(c) pancreatic cells.

(5) In this regulation, "advanced therapy medicinal product" has the same meaning as in the Human Medicines Regulations 2012([7]).

([6]) *See* section 54(6) of the 2004 Act for the meaning of "embryo". That subsection was substituted by paragraph 24 of Schedule 7 to the Human Fertilisation and Embryology Act 2008 (c. 22).
([7]) [*See* regulation 8 of] S.I. 2012/1916 [amendments pending].

Annex A – Snapshot of the proposed new system

Organ Donation current system in 2019/20

- If you wish to donate your organs, you can add your name to the Organ Donor Register (ODR) or make your decision to donate in another way. You can specify whether you want to donate all your organs or only some of them.
- You can also add your name to the Register to say that you do not want to donate your organs or make your decision to opt out in another way (for example, by telling your family).
- You can appoint someone else to make the decision on your behalf after death.
- Your family or someone else, for example a close friend, will be asked what your wishes were and will be fully involved in discussions with the specialist nurse.
- Children below 18 will be excluded from opt-out and will be able to continue registering a decision with parents/guardians giving consent.
- For donation for a rare or novel transplant, your family, close friends or nominated representative would be asked for express consent. You might also give express consent in advance.
- If your organs or tissues could not be used for transplantation, but could be used for research purposes, your family, close friends, or nominated representative will be asked for express consent.
- There will be a 12-month communication campaign starting in late April 2019, to make people aware of the changes, ahead of opt-out starting in 2020.

Organ Donation from 2020 - Opt-out comes into force

- You will still be able to record on the Register and in other ways if you wish to donate your organs and tissues and will still be able to specify whether you want to donate some or all of your organs and tissues.
- You will still be able to record a decision on the Register and in other ways if you do not wish to donate your organs or tissues (i.e. you can opt out).
- You will still be able to appoint someone else to make the decision whether to donate your organs or not after death.

- If you do not do any of the above, the default position from 2020 will be that you will be an organ/tissue donor after death unless you are in an excluded group.

- Subject to the outcome of this consultation, for donation for a rare or novel transplant, your family, close friends, or a nominated representative will still be asked for express consent. You can also give express consent yourself in advance of your death.

- If your organs and/or or tissues could be used for novel procedures, including an Advanced Therapy Medicinal Product (ATMP), your family, close friends, or a nominated representative would be still be asked for express consent.

- If your organs or tissues could not be used for transplantation, but could be used for research purposes, your family, close friends, or nominated representative would still be asked for express consent.

Annex B - List of organs and tissues covered by deemed consent

It is intended that the following organs and tissues will be covered by opt-out:

- heart
- lung(s)
- liver including liver cells (called "hepatocytes"), unless used for an Advanced Therapy Medicinal Product (ATMP)
- kidneys
- pancreas including pancreatic cells (called "islets"), unless used for an ATMP
- intestinal organs (small bowel, stomach, abdominal wall, colon, spleen)
- eye
- nervous tissue
- artery/veins/blood vessels
- bone
- muscle
- tendon
- skin
- rectus fascia (tissues that encases abdominal muscles)