

## Question and Answers on the Human Transplantation (Wales) Act 2013

### 1) What is changing when?

From the 1<sup>st</sup> December 2015 the way people in Wales choose to donate their organs will change to a “soft opt out” or “deemed consent” system. The consent will only apply to the donation of organs and tissues for the purposes of transplantation – for example donation for the purposes of research is not covered by deemed consent.

From that date, people living in Wales will have three choices:

#### **Choose to be a donor by:**

- Registering an express decision to be a donor, as you can now (opting in)
- Doing nothing which means you have no objection to being a donor (deemed consent)

#### **Choose not to be a donor by:**

- Registering an express decision not to be a donor (opting out)

### 2) What does Express consent mean?

The decision of the person in life

The decision of an appointed representative

The decision of a person in a qualifying relationship

The decision of a person with parental responsibility in the case of children

### 3) What does deemed consent mean?

When there is no record of a person's decision on organ donation, or they have not stated to their family that they want to be a donor, their consent will be deemed to have been given. A person with a close relationship may provide evidence that the person did not want to be an organ donor.

Deemed consent changes the default position to one where adults are viewed as having no objection to organ donation unless the evidence is to the contrary.

#### 4) What does “soft opt out” mean?

Soft opt out means that families will still be approached and involved in the conversation about organ donation. In a deemed consent system, families are not asked to give their consent to donation, but can say whether they knew the deceased person did not want to be a donor. This gives families the chance to overturn the “presumption” of consent. This is a change to the way things are done now because the default position will be that the person did not object to donation unless their family can say they did object to it.

#### 5) In what order should consent in Wales be ascertained?

In order of priority:

##### **First person consent**

This means the decision of the person in life. It is up to the individual to decide how to do this. The SNOD should check the ODR and ask family members and friends if the patient had made a decision on organ/tissue donation.

##### **Appointed representative**

The SNOD should check the ODR and/or ask family and friends to establish whether the patient appointed a representative to make a decision on their behalf in regard to organ donation.

##### **Deemed consent** (If applicable)

The SNOD should establish that the patient had not recorded a decision on the ODR, appointed a representative or informed family and friends of their decision in regard to organ donation.

If there is no known decision by the patient to organ donation when they were alive, their consent can be deemed.

##### **Qualifying relationship**

Consent for organ donation must be ascertained from those in the qualifying relationships when none of the above applies.

#### 6) Who in Wales could have their consent deemed?

Consent in Wales can be deemed if **all** the below apply:

- Aged 18 and over (from 00.00 on their 18<sup>th</sup> birthday)

- Adults who have lived in Wales for 12 calendar months or more and are ordinarily resident in Wales in a voluntary capacity
- Adults who have had the capacity to understand the notion of deemed consent for a significant period before their death (12 months)
- Adults who die in Wales.

Deemed consent **will not** apply to anyone living in Wales temporarily or visiting.

When a person is within all of the categories above, it is lawful for their consent to organ donation to be deemed, **unless**:

- They made a decision in life in regard to organ donation
- They appointed a representative/s to make a decision on organ donation on their behalf
- A relative or friend of long standing objects on the basis that the deceased person did not wish to be an organ donor
- The transplant activity involves relevant excluded materials

## 7) How will I know if the patient was ordinarily resident in Wales?

The SNOD should be able to establish whether a person lived in Wales, either from medical records or through discussions with family and friends. The test for ordinarily resident attaches a number of qualities, these are:

- The residence was adopted voluntarily
- The person was resident for settled purposes
- The person's residency in Wales supported the regular order of their life

The SNOD should discuss with family and friends to determine where the patient would refer to as home. If it is not possible within a suitable time frame to establish if the patient lived in Wales deemed consent cannot be applied.

## 8) Are there any people who cannot be considered as voluntarily ordinarily resident in Wales?

People serving in the armed forces who are directed to live in Wales and people who are in prison cannot be considered ordinarily resident in Wales. For both these groups of individuals they cannot have their consent deemed.

There may in addition be other groups of people who may not reside voluntarily in Wales and the SNOD should discuss with family and friends to establish whether they consider residence to voluntary.

### **9) How will I know if the patient had capacity to understand the notion of deemed consent?**

The starting assumption must be that the patient has the capacity to make a decision unless it can be established that they lack capacity in accordance with the Mental Capacity Act 2005.

Where there is evidence of an illness that may have impacted the patient's capacity to understand deemed consent, the SNOD should undertake further investigations which address the specific circumstances and raise their concerns with the family and friends in order to check that the patient did have capacity.

### **10) Who is not affected by deemed consent?**

- A child or young person under the age of 18
- An adult who has lived in Wales for less than 12 calendar months
- An adult who has lived in Wales for more than 12 months but is not ordinarily resident there
- An adult who lacks capacity to understand the notion of deemed consent for a significant period before their death. In practice for a period of at least 12 months before their death.

### **11) Does deemed consent cover organs/tissue for research?**

No, deemed consent does not apply to anything other than the donation of organs and tissues for transplantation. Consent for research or any other purpose continues to be governed by the Human Tissue Act 2004. Express consent will be required for any of those activities.

### **12) How will consent be obtained if the patient is not registered on the ODR, has not appointed a representative or deemed consent does not apply (for example if the patient does not live in Wales)?**

If there is no record of the person's decision and if deemed consent cannot apply to them, then consent should be obtained from a person in a qualifying relationship.

### **13) If there is no decision recorded on the ODR and deemed consent can apply, what evidence is required if family members say that the patient didn't want to be a donor?**

If evidence is presented that states that the person did not want to be a donor a decision will have to be made on the quality of that evidence and whether or not it should be relied on.

The highest quality evidence should be written, signed by the person and witnessed. However, it is unlikely that such evidence would be available and it is far more common for the evidence to be communicated verbally, perhaps based on a conversation that the relative or friend had with the person. This would need to be carefully evaluated for its content and detail, for example, when did the conversation take place, why was the subject being discussed, why didn't the person record their decision, was anyone else present at the time, etc

Staff should sensitively question relatives and friends about such conversations and come to a conclusion as to whether the evidence should be relied on

Any evidence which is relied on should be noted in the person's medical record or other suitable record, for example the consent form.

There is no legal obligation under the HT (W) A 2013 that the person's consent to transplantation is acted upon. However, an offence would be committed if an organ or organs were removed for the purpose of transplantation without appropriate consent. Therefore it is required practice to thoroughly investigate and record any evidence which is presented that the person did not want to be a donor in order to be able to demonstrate that the decision was the last known wishes of the deceased and acted on in good faith.

#### **14) What is reasonable evidence?**

You should consider the following questions when deciding.

- Does the evidence presented reflect the views of the patient or the family?
- Is the written evidence signed and dated by the patient and a witness?
- Is the verbal evidence corroborated by more than 1 person?
- How recent is the evidence, most recent should be relied upon?
- How well does the person providing the evidence know the person?
- What was the context of the conversation in which the person expressed their view – e.g. watching TV programme about organ donation, seeing an advert, reading a leaflet, etc?

**15) If there is evidence provided that the patient does not want to be a donor, does it have to come from someone within the qualifying hierarchy?**

No, the evidence can be provided by any relative or friend of long standing.e.g it may be a cousin, aunt or uncle who provides the information.

**16) What happens if the family say that the reason they registered a decision not to donate was because of the change in legislation in Wales, but they did believe in organ donation?**

The reason for the “no” decision is irrelevant. Legally, a decision not to be a donor must be treated as the person’s decision. To do otherwise would be to second-guess what was in the person’s mind when they registered. However if family members can provide clear evidence that the person had changed their mind then that would be different and might be considered.

**17) If the patient didn’t register a decision and there isn’t an appointed representative and no family or friends are present, can their consent be deemed?**

Possibly, if the clinician felt they could confirm these details from the patient’s notes. However, family and friends are needed to confirm details about the person’s residency, their capacity to understand the notion of deemed consent and whether there was any evidence that the person would have objected. Whilst it is perhaps theoretically possible to gain this information from medical and other records, it would not be advisable since some details may only be known to that person’s family or friends.

**18) If deemed consent applies to the patient what should we say to the family?**

If there is no recorded decision or appointed representative on the ODR the family must be asked whether they are aware of the patient’s decision in regard to organ donation. Family and friends must be given the opportunity to produce evidence that the patient had decided to be or not to be a donor. If there is no known decision in the patient’s life the family must be informed that in such circumstances the patients consent to organ donation can be deemed.

**19) What if I can’t find out if the deemed consent criteria applied to the patient within a reasonable timeframe to enable donation to proceed?**

If the SNOD is not able to establish whether the deemed criteria applied to the patient within the time frame to enable consent to be deemed, for example, it

has not been possible to decide if the person lived in Wales ordinarily, then express consent from those in the qualifying hierarchy should be ascertained

## **20) If an adult Welsh resident dies somewhere else in the UK are we able to deem their consent?**

No. Deemed consent only applies if an adult Welsh resident dies in Wales. If the person dies elsewhere and they have no recorded decision, then the consent of the qualifying relation must be sought.

## **21) How do I know if the patient didn't want to be an organ donor?**

The Act does not require a person to record their decision about organ donation. It is up to the individual to decide how best to do this.

- They can tell a friend or family member
- Appoint a representative to make a decision on their behalf
- Register a decision on the organ donor register which is capable of holding decisions to be a donor (opt in) or decisions not to be a donor (opt out).

## **22) What is the excluded material if consent is to be deemed? (Subject to the final regulations)**

The recognisable whole or recognisable part of the following composite tissue are specified as excluded material

- (a) brain
- (b) spinal cord
- (c) face;
- (d) nose;
- (e) mouth;
- (f) arm;
- (g) upper arm;
- (h) forearm;
- (i) hand;
- (j) finger;
- (k) leg;
- (l) thigh;
- (m) lower leg;
- (n) foot;
- (o) toe.

However, the individual materials which form part of the composite tissue are not in themselves excluded from deemed consent (i.e. eye, nervous tissue,

artery, bone, muscle, tendon or skin). The purpose is to ensure that so-called 'novel' forms of transplantation, such as limb transplants, do not fall within deemed consent, but, for example, a bone from a leg on its own may do so.

The whole or part of the following are also specified as excluded material

- (a) ovary;
- (b) uterus;
- (c) penis;
- (d) testicle;
- (e) foetus;
- (f) placenta;
- (g) umbilical cord; or
- (h) embryo (inside the body).

Express consent would be required for any of the above to be donated

### **23) Tissue Donation: - What Tissues can be deemed under the Act?**

All Tissue's that the SNOD currently gives the option of donating **can** be deemed:

- Eyes
- Heart Valves
- Skin
- Bone
- Tendons
- Meniscus
- Arteries

### **24) Who can be the appointed representative?**

The appointment has to be someone appointed by the patient to make a decision on their behalf in regard to organ donation.

This role is not the same as someone who has lasting power of Attorney relating to personal welfare or has been nominated to act under other legislation.

A child is able to appoint a representative to make the decision on their behalf so long as they are competent to do so.

### **25) How will I know if the patient appointed a representative?**

The name and contact details of the appointed representative may have been recorded on the register. If there is no record then the family and friends of the patient should be asked if they are aware of person/s who was appointed to make decisions on organ donation.



## **26) How will I know that the appointed representative has the authority?**

If the appointed representative's details are on the register this will already have been confirmed by the patient at the time of registration.

If there is no record on the register and you have been informed orally of the appointment you will need to check that the appointment was witnessed by at least two people. This can be orally or written with the two people's signatures confirming they witnessed the appointment.

If the appointment was made in writing you should check the document was signed by the person in the presence of a witness who confirms the signature, OR it was signed by another person at the direction of and in the presence of the person in the presence of a witness who confirms the signature, OR it is contained in a lawfully made will.

## **27) What safeguards does the HT (W) A have for those closest to the patient?**

The law in Wales has several safeguards which mean that families will always have the opportunity to express a view as they always need to be involved in the discussions about organ donation. It would not be possible to determine the below without them:

- The right of the family to object to donation if they know the deceased would have objected (i.e. they will be able to say if they know of an unregistered objection and to therefore rebut the presumption of consent)
- The requirement to establish ordinary residence
- The ability to say if they thought the patient lacked the capacity to understand the notion of deemed consent

## **28) Children and consent to organ donation**

A child is able to give first person consent if at the time of their decision they were competent to make the decision.

- If aged 16-17 the starting assumption is that the child had the capacity to make a decision unless it can be established that they lacked capacity.
- If age 15 and less it is an objective decision by a reasonable person that the child had sufficient understanding and intelligence to understand fully what was proposed. This may involve collecting evidence from family and friends at the time they made the decision.

### **29) Who is able to give consent for a child?**

If a child has not been able to provide first person consent for any reason and has not appointed a representative then consent must be sought from the persons with parental responsibilities.

If there is no one alive with parental responsibility for the child then consent can be sought from a person in the qualifying relationship.

### **30) Can we tell the family that the patient had registered a no?**

Yes, any decision recorded on the ODR is able to be communicated to the family.

### **31) When a patient has appointed a representative what information are we able to tell the family?**

Under Information Governance the SNOD is able to inform the family that the patient has appointed a representative to make a decision about organ/tissue donation on their behalf but NOT who that person is.

The SNOD must gain consent from the appointed representative to be able to inform the family the name of the representative and any contact details.

If the representative does not wish to allow the family to know who they are we are not under any legal obligation to inform the family. This is not in the public interest and must not be overridden.

If the family and appointed representative do not agree with the decision regarding organ donation the SNOD should seek to resolve the disagreement as they would between family member disagreements.

### **References:**

Human Tissue Authority (2014) Code of Practice on the Human Transplantation (Wales) Act 2013  
[https://www.hta.gov.uk/sites/default/files/HTA\\_CoP\\_on\\_Human\\_Transplantation\\_\(Wales\)\\_Act\\_2013\\_-\\_Final\\_-\\_May\\_2014.pdf](https://www.hta.gov.uk/sites/default/files/HTA_CoP_on_Human_Transplantation_(Wales)_Act_2013_-_Final_-_May_2014.pdf)

Human Tissue Authority (2014) Code of practice 2: Donation of solid organs for transplantation. v14.0. <https://www.hta.gov.uk/code-practice-2-donation-solid-organs-transplantation>

Human Tissue Authority (2014) Code of practice 1: Consent. v14.0.  
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Email correspondence from Welsh Govt March 2015

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