

Question and Answers on the new register for organ donation decisions (ODR)

1. Why have we got a new register?

The change in Welsh Legislation meant that the existing Organ Donor Register (ODR) needed to be changed so that it could record decisions **not** to be a donor (i.e. opt-out decisions). The current register was not technically robust enough to accommodate the change and so it was decided by the 4 UK Health Departments that the whole system would be redeveloped to provide additional capacity and functionality.

As well as being able to record opt-in and opt-out decisions, it was also decided to provide the facility on the new register to record the details of appointed/nominated representatives.

NHSBT is leading on the project, which is funded predominantly by Wales with contributions from England, Scotland and N. Ireland.

2. What are the main differences from the current ODR?

The new register will provide a robust platform for the recording of organ donation decisions and the system will be fit for purpose for years into the future. As far as the public users of the system are concerned, there will be three registration possibilities instead of just one. These are:

1. Yes I want to donate all or some of my organs (as is currently the case).
2. No I don't want to donate.
3. I want to appoint /nominate a representative for the purposes of organ donation only.

All three decisions are supported in current practice; the difference being is that individuals will now be able to record all types of decision on the new register.

In terms of the NHSBT users of the system, the new register will provide a number of improved functions and reporting mechanisms and will be more accessible (i.e. via iPad etc.)

3. What happens to all the registrants on the current ODR?

All existing registrations on the current ODR will be migrated over to the new register which will be active for NHSBT and the SNODs to use in May 2015. There will be a soft launch of the new register from 1 June when it will be possible for members of the public to go on and record their decision. This will correspond with the start of the Welsh Government's household leaflet drop, which will tell people the new register is now ready for use.

The full launch of the register will begin on 1 July 2015. People will be able to:

- Change their registration if they wish
- Register yes to organ donation
- Register a no to organ donation
- Appoint/ nominate a representative

4. What if someone has registered more than one decision on the new register?

The register will only hold one decision per individual and there is only one register to check. Once a person has made an initial record on the register any additional registrations will be recorded as amendments. These amendments to a registration will be available for staff to see on the new register. I.e. if an individual originally registered a No to donation and subsequently changes that to Yes this will be available information at the time of searching the register.

The pdf print out; however, will only show the most up to date record

5. How will people know that they are able to record a decision not to be a donor or appoint a representative on the register?

Wales will be promoting the new register as a part of its communications on the new law as this is an integral part of the new opt out/deemed consent system in Wales. As well as other publicity, the Welsh Government will be delivering leaflets to all households in Wales.

The other UK countries are not planning such large scale publicity events because their policies have not changed. We understand the other countries will be issuing a press release to mark the launch of the new register, which they view as a welcome refresh of the system. Scotland may carry out some additional publicity to advise people that they can record a “no” decision, however in general the launch of the new register will not receive the same level of publicity in the other countries as it will in Wales, which is to be expected⁴.

6. How will people be able to record a decision not to be a donor on the new register?

Registering a decision not to be a donor will only be possible via the website www.organdonation.nhs.uk or the call centre NHS Donor Line 0300 123 23 23

This will ensure a decision not to be a donor will be active on the new register within 24 hrs.

Other partner feeds will not have the ability to register a decision not to be a donor. This is because information from those sources takes longer than 24 hours to reach

the register and this could pose a small risk that organs could be donated from someone who did not want to be a donor during the small window when their decision was on its way to the register from the DVLA or other partner feed.

7. What happens if a family member doesn't agree with the patient's decision to donate (opt in) held on the register?

When informing family members of a decision to opt in to organ donation the SNOD should positively encourage the family to support this decision. It should be made clear they do not have the legal right to overrule their relative's decision.

However, there is no requirement that organ donation goes ahead when there is express consent/authorisation, rather that it would be lawful. It will be a decision for the SNOD, with the support of the RM (SMT) In line with MPD 901 and 598 as to whether to proceed to donation when the family clearly object or if they are extremely distressed^{1,3}.

8. What happens if a family member doesn't agree with the patient's decision not to donate (opt out) held on the register?

A decision not to donate (opt out) could not be changed just because the family wanted to donate the organs. The decision must be the decision of the deceased person. Unless the family can produce clear evidence that the person had changed their mind and did in fact want to be a donor (see Question 11 below), the no registration would be adhered to^{1,3}.

9. What happens if a family member states that the patient had changed their mind since registering to donate and that they no longer wanted to be a donor?

The family should be asked why they thought that to be the case, why the person would have objected and what evidence they have to show this is the case. The information provided must satisfy a reasonable person that the patient would not have given consent. It will be unlikely that the family will be able to produce a documented reversal of the person's decision and clinicians are likely to have to rely on recollections of conversations, etc. The evidence should appear to be credible and be the views of the deceased person themselves^{1,3}.

10. What happens if a family member states that the patient had changed their mind since registering to not donate and that they now wanted to be a donor?

It is extremely unlikely that a decision not to donate (opt out) would be changed unless the family can produce clear evidence that the person had changed their mind and did in fact want to be a donor.

Under both the Human Tissue Act 2004 and Human Transplantation (Wales) Act 2013 the family must provide the evidence they believe proves the person did make a

decision to be an organ donor and this decision supersedes their recorded decision not to donate^{1,3}.

The Human Tissue (Scotland) Act 2006 states that part of the body may be removed and used but only when there is authorisation. It is not adequate for a relative to simply say the donor had changed his mind since registering his decision. There would have to be some written or verbal record from the donor to that effect.⁸

11. What evidence is required to show that a patient will have changed their mind since registering on the ODR?

If evidence is presented that states that the person had changed their mind following registering their decision on the ODR, 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 would 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 change their recorded 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 any of the UK legislations that the person's consent/authorisation 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/authorisation. Therefore it is required practice to thoroughly investigate and record any evidence which is presented that the person changed their mind in order to be able to demonstrate that the decision was the last known wishes of the deceased and acted on in good faith.

If relevant evidence is provided and the SNOD accepts that the patient had changed their mind since registering the the SNOD must contact the regional manager on call to discuss. This in turn may then be escalated to the SMT on call and a decision made about the validity of the evidence and how best to proceed^{3,5}.

12.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, etc⁴.

13. 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 considered⁴ .

14. Who can be the appointed/ nominated representative?

The appointment has to be someone appointed/ nominated 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. If the deceased person lives and dies in Wales, the person appointed would need to satisfy any requirements set out in Regulations made by Welsh Ministers^{1,3}.

In Scottish law an appointed/nominated representative is not recognised, as such any recorded decision for an appointed /nominated representative will not be acted on if the patient dies in Scotland^{6,7} .

15. Does the appointed/ nominated representative need to be an adult?

Yes. Under the HTA 2004 and HT(W)A 2013 a child cannot act as an appointed/nominated representative^{1,2,3}.

16. Can people living in Scotland register an appointed/nominated representative on the register?

Yes. They are able to record that decision on the register. If they die in Scotland that decision will not be acted upon and the qualifying relationship will be enacted to obtain authorisation.

If the individual dies in England, Wales or N. Ireland then the appointed/nominated representative will be contacted ².

17. 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 new register.

If there is no record then the family and friends of the patient should be asked if they are aware of any person(s) who have been appointed to make decisions regarding organ donation. Once established that there is an appointed representative the SNOD should contact them and ask them to make a decision on behalf of the patient ^{1,3}.

18. 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 verbally 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 ^{1,3}.

19. If there are 2 appointed/nominated representatives do we have to ask both for a decision on organ donation?

In both the HTA 2004 and the HT(W)A 2013 if more than one person has been appointed/nominated, unless the appointment provides that they are appointed to act only jointly, the default position is that the appointed representatives can make the decision jointly or separately. This means that they do not have to agree, so one can give consent regardless of what the other representative decides ^{1,3}.

20. If the first representative we ask says no are we able to then ask the second representative to see if they will say yes?

Reasonable efforts should be made to contact both representatives in order to give them both the opportunity to state their views. If they can both be contacted and they disagree then the SNOD should treat the situation as they do now with families who disagree and try to gain consensus.

If after reasonable efforts only one of them can be contacted the decision of that person should be taken as final without further efforts made to contact the other one⁴

Further information from the HTA may become available and will be added to the next version of this document

21. What if we are unable to contact the appointed/nominated representative or they are unwilling to make a decision?

If the appointed/nominated representative cannot be contacted in time to make a decision, or is unwilling to make a decision, then a person in a qualifying relationship may be approached to make a decision about organ donation or a person with parental responsibility in the case of a child^{1,3}.

22. Can a child appoint/ nominate a representative?

Under the Human transplantation (Wales) Act 2013 a child can appoint a representative to make the decision about organ donation on their behalf.

Under the HTA 2004 a child cannot appoint a nominated representative relating to seeking consent for organ donation^{1,3}.

23. What is a SNOD allowed to say to the appointed/nominated representative if, when they contact them, they are not aware of the patient's illness or death?

As part of registering the appointed/nominated representative a statement on the registration form will need to be checked by the ODR registrant.

"I agree that if I am in a position to donate my organs/tissues, that you will be contacting my appointed/nominated representative you will have to give them some information about my medical condition"

This will be confirmed in the letter of confirmation sent to the ODR registrant that their appointed/nominated representative is now active on the ODR.

As such minimal information about their medical condition will be able to be discussed with the representative to aid them in making a decision regarding organ donation

24. When does the Human Transplantation (Wales) Act 2013 become Law?

The HT (W) A 2013 sets out how consent is able to be given in Wales. It does not require a person to record their decision about organ donation in a specific manner. It comes fully into force on 1 December 2015.

From that date, in Wales, if no decision has been recorded on the register and the patient did not tell their family etc, then if they are eligible, deemed consent can be applied. If deemed consent cannot apply to the person (e.g. because they are not ordinarily resident) then consent will be obtained via the qualifying relations.

25. If there is a recorded decision on the register not to donate any organs do we have to mobilise to the hospital to speak to the family?

It is considered best practice by NHSBT operational management that during working hours, or if the on call SNOD is close to the referring hospital, for a SNOD to inform the relatives in person of the decision recorded on the register. If out of hours and the on call SNOD is some distance away from the referring hospital or donation activity doesn't allow for a face to face conversation this conversation can be had by telephone.

The approach should be made using the suggested sentence below.

"Your relative recorded a decision on the Organ Donor Register to say they did NOT want to be a donor. This will be the decision we will be relying upon unless you have any other information you'd like to bring to our attention."

26. If the patient has recorded a decision not to be a donor on the register but the family have brought up donation in a positive way, do we mobilise a SNOD?

It is considered best practice by NHSBT operational management that during working hours, or if the on call SNOD is close to the referring hospital, for a SNOD to inform the relatives in person of the decision recorded on the register. If out of hours and the on call SNOD is some distance away from the referring hospital or donation activity doesn't allow for a face to face conversation this conversation can be had by telephone.

The decision to proceed with organ donation when the registration on the ODR is not to donate must be discussed with the Regional Manager on call. The evidence provided must be that the registrant had changed their mind and not that the family don't agree and want organ donation to proceed.

27. Will the organs and tissues listed on the current ODR change in the new register?

No all the organs and tissue listed on the current ODR will remain the same. Any organs or tissue not listed where consent/authorisation is required will have to be ascertained from either the appointed/nominated representative or those in the qualifying relationship.

28. Does the new register allow a decision in respect of research?

There are no plans currently to enable registrants to be able to consent to research via the website. This may be reviewed at a later date.

If the registrant is registering via the call centre that question will be asked and the response recorded on the ODR.

An unchecked box or the absence of a decision on the ODR does not mean that the registrant has not given consent and the question will need to be discussed with those involved in the donation conversation.

Further question may be added to this document and future versions will be sent out and stored in document control.

If you have any additional questions please send to

WelshLegislationProject@nhsbt.nhs.uk

References:

1: 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>

2: Human Tissue Authority (2014) Code of practice 1: Consent. v14.0. <https://www.hta.gov.uk/code-practice-1-consent>

3: 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)

4: Email correspondence from Welsh Govt March 2015

5: Email correspondence from The Human Tissue Authority January 2015

6: Human Tissue (Scotland) Act 2006:
http://www.legislation.gov.uk/asp/2006/4/pdfs/asp_20060004_en.pdf

https://www.hta.gov.uk/sites/default/files/Information_about_HT_%28Scotland%29_Act.pdf

7: Human Tissue (Scotland) Act 2006 explanatory notes:
<http://www.legislation.gov.uk/asp/2006/4/notes/contents>

8. Senior Counsel opinion in the matter of advice on organ donation. Letter format

