

NHS BLOOD AND TRANSPLANT

NATIONAL ORGAN DONATION COMMITTEE

Human Transplantation (Wales) Act 2013 Changes required to the Potential Donor Audit and Referral Record Data Sets

BACKGROUND

The Welsh Government is implementing the Human Transplantation (Wales) Act which comes into force on 1st December 2015. The Act introduces a system of presumed consent and provision to allow citizens to record an opt-out preference should they wish. NHSBT will operate the new arrangements on behalf of the Welsh Government, this will include a new Organ Donor Register (ODR) to cover the additional functionality required; the new ODR will cover all four nations of the UK. The new legislation and ODR will require business change in the form of new processes and procedures and training. This includes changes to the Potential Donor Audit (PDA) and Referral Record forms where SN-ODs capture an individual's preference in relation to donation if known.

SCOPE OF CHANGE

The PDA and Referral Record data sets will require updating to capture where the Human Transplantation (Wales) Act is applicable to a patient and where an opt-out decision had been recorded on the ODR. Amendment to the approach and consent questions will be made to reflect the new processes followed by SN-ODs and to ensure a single version of the PDA and Referral record is applicable to and functional in all four nations of the United Kingdom.

Changes to the data sets will need to be reflected in the Electronic Offering System (EOS) which is used by SN-ODs to submit data. The reporting module of EOS will also require updating to ensure that calculations of the consent/ authorisation rate exclude approaches to families of patients who have opted out under Welsh legislation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006. This group of patients will be reported separately.

Full details of the changes to the data sets can be found in Appendix 1.

The aim is to implement these changes in EOS on 1 July 2015.

PROCESS

A sub-group of the National Organ Donation Committee was convened to identify and document the changes required to the PDA and Referral records. The sub-group members were:

Alex Manara – Consultant Anaesthetist / PDA sub-group Chair
Karen Morgan – ODT Regional Manager (South West & South Wales)
Joanne Allen – Senior Statistician, NHSBT
John Richardson – Head of Health Informatics, NHSBT

ACTION

The sub-group seek ratification from the NODC in relation to the approach taken and suggested changes to the PDA and Referral Record data sets.

John Richardson
Head of Health Informatics

October 2014

Appendix One	
Amendments to the PDA and Referral Records in response to the new ODR	
ODR Section	
1	<p>Addition of a question in the middle of the ODR section of the forms (immediately below 'Who consulted the ODR? If other please specify') to read:</p> <p>Does Welsh legislation apply to this patient? i.e. Have they:</p> <ul style="list-style-type: none"> - Died in Wales aged 18 or over at the time of their death, and - Lived in Wales for more than 12 months <u>and</u> is ordinarily resident there, and - Had the capacity to understand the notion of deemed consent for a significant period before their death <p>The possible answers to this question are YES or NO</p>
2	<p>The question 'Had the donor expressed a wish to donate in their lifetime?' will be replaced with 'Had the patient expressed any decision in relation to donation in their lifetime?'</p> <p>The possible answers to this question remain YES, NO or UNKNOWN.</p>
3	<p>The question above will be followed with a new question: 'If YES, what was the patient's decision?'</p> <p>The possible answers to this question are 'To donate (Opt-in)' or 'Not to donate (Opt-out)'.</p> <p>This will be followed by 'Method by which the patient choice was expressed? Please answer Yes (2), No (1), or Unknown (9) to each of the following questions (at least one option must be answered YES)'</p> <ul style="list-style-type: none"> - Registered on the ODR – YES or NO - Expressed their wishes verbally or in writing – YES, NO or UNKNOWN - Via a nominated / appointed representative – YES, NO, NOT APPLICABLE or UNKNOWN - Carried a donor card – YES, NO or UNKNOWN - Written a will with their wishes specified – YES, NO or UNKNOWN
Consent Section	
4	<p>The question 'Were the family formally approached for consent / authorisation for solid organ donation?' will be replaced with 'Were the family formally approached to discuss the patient's decision regarding solid organ donation?'</p> <p>The possible answers to this question remain YES or NO.</p>

5	<p>Addition of a question following the question 'Where was the formal approach made?' The new question is 'Was consent deemed under Welsh legislation?'</p> <p>The answer to this question will be pre-filled and non-editable:</p> <ul style="list-style-type: none"> - The question will be answered YES if the ODR question 'Does Welsh legislation apply to this patient?' is answered YES and the answer to 'Had the patient expressed any decision in relation to donation in their lifetime?' is NO or UNKNOWN - The question will be answered NO if the ODR question 'Does Welsh legislation apply to this patient?' is answered NO regardless of the answer to any other questions in this section. - The question will also be answered NO if the ODR question 'Does Welsh legislation apply to this patient?' is answered YES and the answer to 'Had the patient expressed any decision in relation to donation in their lifetime?' is YES
6	<p>The question 'Was consent / authorisation for solid organ donation given by the family?' will be replaced with 'Did the family agree to solid organ donation proceeding?'</p> <p>The possible answers to this question remain YES or NO.</p>
7	<p>The reason 'Patient had previously expressed a wish not to donate' will be added to the code lists for:</p> <ul style="list-style-type: none"> - Reason neurological death tests not performed (to appear above 'Family declined donation' in the picklist) - Reason patient not discussed with SN-OD (to appear above 'Family declined donation prior to neurological testing' in the picklist) - Reason permission not requested from Coroner / Procurator Fiscal (to appear above 'Family declined donation' in the picklist) - Reason family not formally approached (to appear above 'Family stated that they would not consent/authorise before they were formally approached' in the picklist)
8	<p>The calculation of the consent rate will need to change. Currently consent rate = 'Was consent/authorisation for solid organ donation given by the family?'/ 'Were the family formally approached for consent/authorisation for solid organ donation?'</p> <p>It is recommended that this is changed to: Consent rate = 'Did the family agree to solid organ donation proceeding?' / 'Were the family formally approached to discuss the patient's decision regarding solid organ donation?'. It is important to note that it will be necessary to exclude the group of patients where 'If YES, what was the patient's decision?'='Not to donate (Opt-out)' from the denominator to ensure that only families approached for a decision to agree to organ donation proceeding are included in the denominator. I.e, it is not relevant to include families in the calculation if they were approached purely for the purpose of informing them that the patient had expressed an 'Opt out' decision on the ODR.</p>
9	<p>Other calculations will also need to change such as consent rate when patient on the ODR</p>