

NHS Blood and Transplant response to the consultation by the Health and Social Care Committee of the National assembly for Wales on the Human Transplantation (Wales) Bill

These comments should be read along side our response to the consultation on the draft bill submitted in September 2012.

NHSBT will respond to the specific points identified in the letter inviting responses to the consultation issued on 6th December 2012.

1. The individual provisions set out in the Bill—

Section 2, relating to the promotion of transplantation,

Section 2 of the Bill places Welsh Ministers not only under a general duty to promote transplantation in order to improve the health of the people of Wales, but also under a more specific duty to ensure people are aware of the arrangements for deemed consent.

Transplantation is a medical procedure and we do not believe it is the intention of the Bill to promote one treatment over another, we therefore believe both the Bill and the explanatory memorandum should be amended so that the duty is to promote “organ donation for the purposes of transplantation.”

Section 3, relating to lawful transplantation activities,

NHSBT has no comments on Section 3.

Sections 4-8, relating to consent,

Paragraph 30 of the Explanatory Memorandum states that if an appointed representative, appointed under section 7, is not contactable then no further attempt will be made to secure consent.

Under the Human Tissue Act 2004 if an appointed person is unable to give consent then the power to make that decision can devolve down the list of qualifying relationships. We would favour this situation being maintained.

Additionally it is not clear from the bill or the explanatory notes how the decision to appoint a representative would be recorded.

We would favour regulations made under section 8(2)(b) being published to coincide with the provisions of the bill coming in to force.

Sections 9-11, relating to offences,

NHSBT has no comments on Section 12.

Sections 12-20, which make general provision.

Inclusion of the word ‘deceased’ in 12(1) marks a significant change from the equivalent section of the Human Tissue Act 2004 (Section 43). It is possible that the addition of the word ‘deceased’ in that section would result in a reduction in donations as preservation activity could only be undertaken once a donor was deceased, this would hit numbers of DCD donors, and would likely prevent hospitals from engaging in pre-mortem optimisation. We believe that for the

avoidance of confusion the word 'deceased' should be removed from that section.

Section 17(6) states that references to transplantation shall include transfusion. While this is identical to Section 54(3) of the Human Tissues Act 2004 we believe that the reference to transfusion in the 2004 act was intended to ensure that blood products, transplantation and transfusion are included in the criminal offence of commercial dealings in Section 32 of the Act, as section 15(5) of the act specifically excludes blood and blood products from the regulatory remit of the Human Tissue Authority. As the Human Transplantation (Wales) Bill does not address the criminal offence of commercial dealings, we believe that for the sake of clarity it is important to add; blood, blood products, blood components and stem cells to the list of exceptions contained in Section 16(2) of the bill.

2. Any potential barriers to the implementation of these provisions and whether the Bill takes account of them.

The new UK wide register which will be developed as a consequence of this bill needs to retain the confidence of the general public as well as the medical community. Care will have to be taken while developing the new register to ensure it retains its existing role as a register of people's wishes and at the same time develops a new legal role as a register of people who have opted-out.

3. Whether there are any unintended consequences arising from the Bill.

While the primary focus of this bill is to introduce a system of deemed consent in Wales we are worried that including references to living donation could lead to misunderstanding. We would favour references to living donation being removed from the bill and the Human Tissue Act 2004 remain the legal basis of living donation in Wales.

4. The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact Assessment), which estimates the costs and benefits of implementation of the Bill).

We welcome the verbal commitment from the Welsh Government regarding funding for the redevelopment of the register and the implementation of the system, we look forward to this being confirmed in writing.

5. The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in Part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation).

NHSBT has no comments on powers in the Bill for Welsh Ministers to make subordinate legislation.

Draft Human Transplantation (Wales) Bill and Explanatory Memorandum:

Consent to organ and tissue donation in Wales

Consultation response form

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Address:	Oak House Reeds Crescent
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Organisation (if applicable):	NHS Blood and Transplant

Are you responding as a (please tick one):

Health- related organisation	<input checked="" type="checkbox"/>
Individual with a health interest (e.g. working in the NHS)	<input type="checkbox"/>
Political Interest e.g. town council, MP	<input type="checkbox"/>
Religious, humanist or ethical organisation	<input type="checkbox"/>
Voluntary sector organisation	<input type="checkbox"/>
Academic bodies	<input type="checkbox"/>
Statutory Commissioner	<input type="checkbox"/>
Member of the public	<input type="checkbox"/>
Other	<input type="checkbox"/>

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Returning this form

The closing date for replies is **10 SEPTEMBER 2012**

Please send this completed form to us by post to the Organ Donation Legislation Team, Medical Directorate, 4th Floor, Cathays Park Cardiff, CF10 3NQ or email to organdonation@wales.gsi.gov.uk

If you are sending your response by email, please mark the subject of your email:
Consultation on the Draft Human Transplantation (Wales) Bill

Alternatively, the consultation responses form is available for completion at www.wales.gov.uk/consultations/healthsocialcare/organbill/?lang=en

Consultation questions

Question 1

Have the concepts of deemed consent and express consent been explained clearly enough?

Yes No

With reference to paragraph 30 of the explanatory memorandum - Where a person who has been appointed to deal with the issue of consent to organ donation and is unable to give consent, paragraph 30 states that no further effort will be made to seek consent. Under the current law if an appointed person is unable to give consent then the power to make that decision can devolve down the list of qualifying relationships. We would favour this situation being maintained.

We believe the bill should set out clearly whether deemed consent will allow pre-mortem interventions to support organ donation which might otherwise be considered in the patient's best interest where there is express consent. This would enable more organs to be preserved for transplantation. . Section 13 of the draft bill 'Preservation for transplantation' is copied directly from the Human Tissue Act and makes it clear that the preservation of a body which may be of use for transplantation is allowable until it has been established that consent for organ donation has not been given or will not be given. It would be helpful if the draft bill could make it clear that deemed consent is sufficient to authorise pre mortem interventions that preserve the potential for donation, possibly by adding a line to section 17 of the bill saying ""consent" means deemed consent or express consent which has the same meaning as in Sections 4, 5, 6, 7 and 8 of this Act".

Question 2

Is the role of the family clear?

Yes No

With reference to paragraph 44 of the explanatory memorandum - we believe that Scenario A needs to set out more clearly how a reasonable person will determine whether the evidence presented is enough to convince them that organ donation should not proceed. This should include what would constitute evidence in law and if there is any time limit on how long ago that information can have been presented to the person making the objection, for example would a half remembered conversation 15years ago be sufficient evidence. The bill needs to minimise any room for doubt in order to support clinicians who will have to make such judgements about what a 'reasonable person' would think in the midst of what is usually a highly emotional situation. Clarity will also help avoid any unreasonable delay and unnecessary intervention to preserve organs until the situation can be established either for or against donation. We think it is unlikely that a family would have written evidence to hand at the time of the donation conversation.

We believe that Scenario B should be more explicit about the need to honour the legally expressed wish of the deceased to be a donor and state that families will be

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asked to help make their relative's wish a reality by providing information about the donor's social and medical history to enable donation to go ahead safely. We support the suggestion that where, in an exceptional case the family refuses to honour their relatives wishes, they should be asked to sign a declaration indicating that they take responsibility for overruling their relative's will in this matter.

Question 3

Are the arrangements for the registration of wishes clear Yes No

Comments-

We support the view that one single register will minimise the risk of incorrect decisions being made.

There are risks with relying on an NHS number as a unique identifier. Ten per cent of the people on the ODR do not have an NHS number. There are cases of a single person having more than one NHS number, and NHS numbers have in the past been duplicated between the four UK health departments. This could lead to any records based on that number carrying conflicting information, being incomplete or out of date.

When a new registration to the organ donor register is received by NHSBT we currently cross reference each registration with the National Clinical Spine, a dataset maintained by NHS Connecting for Health (the same national system as GPs use to record new patients). That person can then be identified as an organ donor and any changes in their address or name recorded by their GP are fed back to the ODR so the record can be updated. This process will need to be carried out simultaneously to ensure that clinicians can be confident they are following the last known wishes of the deceased.

We are also concerned that, if an NHS number is necessary to join the new register then people will find it difficult to opt out or opt in as they struggle to remember or locate their NHS Number. Will it be possible to register if you do not know your NHS number?

Although the proposed approach is to have one register in Wales it will mean that there are two registers in the UK with specialist nurses in England, Northern Ireland and Scotland needing to check two registers to be sure a potential donor has not lived in Wales for six months or more when aged over 18. This may not present much of a problem shortly after the legislation is introduced but the risks will grow with each passing year. To illustrate the problem consider a woman who lives in Wales until her early 20s and opts out of organ donation. If she moves to another part of the UK, marries and changes her name then her opt out on the Welsh register is a valid decision about organ donation under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, unless she later changes her mind and opts in to the NHS ODR. Specialist nurses will need to establish whether any potential donor throughout the UK might have lived in Wales and opted out in the past. This will be time consuming and could lead to unacceptable operational risks if there is any delay

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in updating either register. It also presents a risk of misidentification if the individual has used different names, addresses etc to register on each database.

The only way to ensure that someone's last recorded wish is captured and retrieved accurately and is available for SNODs is to have a single register across the UK capable of recording the wishes required by the relevant administration. We will assess the resource implications and discuss the options with the four health departments.

The list given under paragraph 59 of the explanatory memorandum should be amended to include 'accessible to appropriate authorised personnel'.

With reference to paragraph 65 - it needs to be clear whether the details identified as a 'minimum' will be a mandatory part of the new register.

A specification for a register needs to be developed which will cover the following points: how will the register be populated and by whom, implementation of safeguards to ensure only those people eligible to register are able to do so; defining the relationship with the existing NHS ODR (for example will it be a replacement with Welsh records migrating, on which organs and tissues will people be able to record a decision, will the two registers be linked and aligned or will they be totally separate); authorising access to the register; clarifying whether the register will be bilingual or available in other community languages. Agreement will also need to be reached on whether the register covers Wales only or whether it could be scaled up to include other nations if desired.

We also believe that the new register should capture information about tissue donation if deemed consent also applies to tissues. The Welsh Government will need to consider whether information should be general or specific. Currently the tissues which can be donated are:

Bone (normally long bones from the leg but also pelvis and humerus occasionally)

Skin

Tendons (Achilles, Semi-tendinosis, Patella, Tibialis Anterior (there is a small demand from surgeons for peroneous longus))

Meniscus

Heart Valves and vessels

Eyes

Infrequently - trachea

Under the new legislation, we think it should be made clear that deemed consent applies only to those organs and tissues listed on the register. Consideration should be given to whether/how the list should be amended when new forms of organ and tissue transplantation become routine. We think it would be helpful to clarify how novel forms of transplantation will be handled. For example people should know that novel forms of transplantation, e.g. face and limbs are excluded and their family will be asked to take this decision on their behalf.

The inclusion of tissues in the Bill may give rise to expectations about tissue donation that would not be fulfilled. NHSBT collects tissue only in North Wales and

currently has an adequate supply. Other organisations collect eyes and heart valves only in South Wales.

Question 4

Are the arrangements for establishing residency clear? Yes No

In determining whether a person has met the residency requirements NHSBT will rely on the family or next of kin to help establish the relevant information including whether the deceased is resident in Wales and for what period of time.

It is proposed that an address will be treated as being in Wales if it falls into the local 'gazetteer' of a local authority in Wales as postcodes are unreliable on the Welsh/English border. It would be helpful if the legislation could clarify whether the Gazetteer should be checked at the point of donation or will the clinicians talking to the family rely on them to establish Welsh residency.

While it will in most cases be simple for NHSBT staff to establish residency, deciding whether or not someone has had "an opportunity to opt-out if that is their wish" is far more subjective and not a judgement NHSBT staff will be able to make. It would be helpful if the legislation could establish clearly a time period after which everyone would be assumed to have had the opportunity to opt-out and deemed consent would apply. This will be particularly important as people approach their 18th birthday so they know whether they need to make their opt out decision before or after this date.

Paragraph 26 and paragraph 40 of the explanatory memorandum need to be consistent. Paragraph 26 says the arrangements will include people studying in Wales, where as Paragraph 40 says people who are working or studying in Wales during the week but returning to a permanent home at weekends will not be. Clarification is needed on this point.

Paragraph 25 states that if a person's address is in Wales, if they generally live at that address, and they have lived at that address or another address in Wales for more then six months they can be considered to live in Wales, however a person living in Wales during the week and returning to a permanent home in England at weekends could fulfil the three requirements yet paragraph 40 states they would not be covered.

Question 5

Does the Equality Impact Assessment properly set out how legislation will affect different sections of society, including children and people who lack capacity? Yes No

The Bill and the explanatory memorandum need to provide sufficient clarity on who will make a decision as regards to capacity and how that capacity will be assessed.

Although the issue of capacity may emerge during the donation conversation, it needs to be clear whether the Specialist Nurse should formally ask the family about their relative's mental capacity and whether it is legally acceptable to rely on their response.

Question 6

The outline for the communication plan is shown in the Explanatory Memorandum. Do you feel reassured that the Welsh Government is planning the public information campaign thoroughly?

Yes No

While we are confident that the extensive communications plan that the Welsh Government has put in place will be effective, it is still possible that there will be some people who are not aware of the new arrangements. We would appreciate guidance on what to do in a situation where a family claim ignorance of the new law even after the publicity and engagement campaign which the Welsh Government has planned.

Who will be responsible for writing to someone who is approaching their 18th birthday and what database will be used? Any data protection and medical confidentiality concerns regarding sharing of information between, for example, NHSBT and a local authority or two NHS bodies will need to be addressed

Paragraph 35 of the explanatory notes goes on to say that 18 year olds will be given 'enough time' to decide whether they will opt in or out. It needs to be clear what is meant by 'enough time'. Will it be the case that, in effect, no one under the age for 18 years and 6 months will be subject to deemed consent?

Question 7

We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Reference to Transfusion

Section 17(3) of the draft bill states "In this Act, references to transplantation are to transplantation to a human body and include transfusion.". For the sake of clarity we believe it is important to add: blood, blood products, blood components and stem cells to the list of exceptions contained in Section 16(2) of the draft bill.

Duty to Promote Transplantation

Section 2 of the Bill places Welsh Ministers not only under a general duty to promote transplantation in order to improve the health of the people of Wales, but also under a more specific duty to ensure people are aware of the arrangements for deemed consent.

Transplantation is a medical procedure and we do not believe it is the intention of the Bill to promote one treatment over another, we therefore believe both the Bill and the explanatory memorandum should be amended so that the duty is to promote "organ donation for the purposes of transplantation."

Living Donation

It is clear that the primary focus of the Bill is to change the system consent for deceased organ donation to an “opt-out” system. We believe reference to living donation could cause confusion.

Tissues

The inclusion of tissues in the Bill may give rise to expectations about tissue donation that would not be fulfilled. NHSBT collects tissue only in North Wales and currently has an adequate supply. Other organisations collect eyes and heart valves only in South Wales.

List of Organs and Tissues

Paragraph 20 of the explanatory notes provides a list of organs covered by the soft opt-out legislation. Tissues are not mentioned and the legislation should be clear about whether all or specific tissues are covered. It will also be important to clarify the position with regard to novel forms of organ and tissue transplantation e.g. face, limbs, uterus, and larynx.

Paragraph 54 of the Explanatory Memorandum

This should be amended to reflect the wording of Section 15(1)(b) of the draft Bill. We would propose changing the wording to “Section 15(1)(b) of the Bill allows for organs donated in Wales under deemed consent to be lawfully used for transplants undertaken outside Wales.”

Partnerships

NHSBT’s partnerships with Boots and the DVLA have proved very successful and result in a significant number of additions to the ODR. While the mechanism for registering through the DVLA is currently available in English and Welsh, this is the only partnership that provides a bilingual service.

Paragraph 66 of the explanatory notes states that ‘all registration mechanisms will be available bilingually and in a variety of other languages’. We are concerned that requiring our existing partners to provide services in a variety of languages could make them less inclined to work with us and result in a drop off in registrations from those sources.

Confidentiality

Responses to consultations may be made public – on the internet or in a report. Normally the name and address (or part of the address) of its author are published along with the response, as this helps to show the consultation exercise was carried out properly.

If you would prefer your name and address to be kept confidential, please tick here:

If you would prefer your response to be kept confidential, please tick here:

