



## **Consultation on draft Legislative Competence Order relating to organ and tissue donation for the purposes of transplantation**

### **Response from Anthony Nolan**

#### **Background**

The Welsh Assembly Government is seeking competence to legislate on the use of human organs and tissues for transplantation. This is currently under the remit of the British Government, which is planning to implement a “mandated choice” system for cadaveric organ donation, whereby applicants for a driving licence will be required to specify whether they wish to allow their organs to be used for transplantation in the event of their death.

Once the Welsh Government has competence in this arena, it has stated it intends to legislate for a “soft” opt-out system for organ donation where it is presumed that a deceased person has consented to the donation of their organs and tissues unless they have signed a register or otherwise declared the contrary. This system is “softened” by empowering a clinician to disregard this presumed consent in the event of serious distress to the family of the deceased.

#### **Concerns for Anthony Nolan**

The draft Legislative Competency Order is framed entirely in the context of cadaveric organ donation. This is because the person donating, having died, must have their consent determined by some means. A living donor, for example of a kidney or a heart in the case of a domino transplant, has the capacity to consent to donation, so legislation is not required in order to make that determination.

Similarly, legislation is not required for peripheral blood stem cell collection nor for bone marrow harvesting as in both cases the donor has capacity to consent. However, the quirk of umbilical cord blood donation is that the cord demonstrably “belongs” to the newborn child and that it is broadly a matter of convention and common sense that the mother has authority over the use of the tissues. Where a mother consents to the collection of her child’s umbilical cord blood, again legislation is not required, however, legislation would become necessary if Wales wished to move to a system of presumed consent for the collection of umbilical cord blood and tissues similar to that proposed for cadaveric donation.

A further concern is that this is a one-time opportunity for cord blood collection in Wales. The process of a Legislative Competence Order, having to be passed by

Legislative Committee, Assembly, House of Commons, House of Lords and ultimately the Queen, means that it is unlikely that a future LCO would be prioritised solely for the purpose of enabling umbilical cord blood and tissue collection.

In short, we are seeking amendments to the Legislative Competence Order that include umbilical cord blood and tissues as a separate class of tissues for which the Welsh Government may legislate to determine the consent for donation. Furthermore, Matter 9.3 should be amended to reflect that in the class of tissues in which umbilical cords would be included, the donors are by definition without capacity and powers should not be excluded on that basis.

Unlike Scotland, England and Northern Ireland, there is no cord blood collection unit in Wales.

### **The benefits of the collection of umbilical cord blood and tissues**

Firstly it is clear that in amending this LCO to encompass umbilical cord blood collection, it does not necessarily follow that the Welsh Government will decide to legislate to presume consent for donation. However, were it to consider doing so, and that would only be possible were the LCO amended accordingly, then the following issues would become relevant.

1. Stem cells collected from umbilical cords are used for blood stem cell transplants. Cord blood has the potential to obviate the need for adult stem cell donation, however, due to the shortage of cord units, most transplants are still undertaken using donations from adult volunteers who have either had stem cells collected over a period of hours from their blood stream or from their bone marrow, harvested under general anaesthetic. Unlike cord blood units which are stored in specialist facilities, even if a matching donor is readily available, the collection process takes time that can impact on the prognosis for the patient.
2. Cord blood and tissue stem cells are also valuable for medical research and in some cases provide an alternative to more controversial research with embryonic tissues.
3. Umbilical cord blood stem cells are broadly advantageous for patients<sup>1</sup>;
  - There is evidence that transplants of cord blood stem cells are successful at a lower degree of tissue matching to the patient than with mature stem cells harvested from adult donors<sup>2</sup>. This means that umbilical cord blood stem cells can be used for some patients who cannot find a matching adult donor.
  - Cord blood stem cells are biologically naïve and are more likely to proliferate than stem cells donated by adults.

---

<sup>1</sup> [http://www.nhsbt.nhs.uk/pdf/uk\\_stem\\_cell\\_strategic\\_forum\\_annex.pdf](http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_annex.pdf)

<sup>2</sup> Shaw, B. E. *et al.* (2009) Recommendations for a standard UK approach to incorporating umbilical cord blood into clinical transplantation practice: conditioning protocols and donor selection algorithms. *Bone Marrow Transplantation*

- The nature of cord blood is that it carries a low potential for infectious disease transmission, a particular vulnerability for transplant patients.
- Stem cells from adults have potentially accrued a far greater degree of genetic damage and modification than those derived from umbilical cords.

4. Patients who benefit from stem cell transplants are usually people diagnosed with blood cancers or other blood and marrow disorders. One in 20 of all cancers diagnosed in Wales each year - about 1,000-1,200 people - are diagnoses of blood cancers<sup>3</sup>.

5. Almost every umbilical cord in Wales is disposed of as medical waste, without any determination of the child or mother's consent. It is likely that some samples are collected for research purposes and there is a small market in private cord blood and tissue collection, despite the questionable efficacy of this practice<sup>4</sup>.

6. Due to the global relationships between stem cell registries, Welsh blood cancer sufferers benefit from stem cell donations and cord blood units from all over the world. However, locally collected units are;

- Less costly to the NHS
- More likely to be a tissue match to a local patient
- Less prone to collection and transport delay
- Of a quality that can be overseen and scrutinised locally

7. Medical academics are exploring how blood stem cell transplants can be used to treat other immunological disorders and diseases including HIV<sup>5</sup>.

8. Mesenchymal stem cells sourced from umbilical cord tissue itself are being explored as a treatment for a range of conditions including spinal cord injuries<sup>6</sup>. While this work is not within the remit of Anthony Nolan, we are seeking an amendment to the LCO that would cover the umbilical cord tissues as well as the blood products derived from them.

---

<sup>3</sup> <http://www.wales.nhs.uk/sites3/page.cfm?orgid=242&pid=27758>

<sup>4</sup> ASBMT <http://netcord.affiniscap.com/associations/8311/files/CordBloodPosition.pdf>

<sup>5</sup> <http://clinicaltrials.gov/ct2/show/NCT00005785>

<sup>6</sup> <http://www.cmj.org/Periodical/abstractlist.asp?titleid=LW2009119599881206142>

## Conclusion

Anthony Nolan supports the aim of the LCO for the Welsh Government to obtain the powers to legislate to determine consent for human organ and tissue donation. We ask for this to be amended to include specifically tissues otherwise normally discarded at childbirth, where the child's consent to donate must be determined.

Furthermore, we ask that the LCO is amended to reflect that in the class of tissues in which umbilical cords would be included, the donors are by definition without capacity and powers should not be excluded on that basis.

If required, Anthony Nolan is prepared to give supplementary oral or written evidence to the Legislative Committee.

### Contact:

Alexander Hilton

Policy & Public Affairs Manager

Anthony Nolan

[alex.hilton@anthohnolan.org](mailto:alex.hilton@anthohnolan.org)

07920 586 281

0207 284 8283