

**Briefing paper on the desirability to foster storage for research and therapies of  
umbilical cord blood stem cells,**

Prepared by

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Context:

Human Fertilisation and Embryology Bill:

Amendment NC3 proposed by Robert Key & others

Summary:

Therapies based on human umbilical cord blood cells have a great potential to cure a range  
of serious and debilitating diseases.

Cord blood is usually discarded at birth but is rich in adult stem cells, which are increasingly  
used as an alternative to bone marrow for transplantation. Umbilical blood may also contain  
pluripotent stem cells, which might be used to repair damaged tissues in a range of  
diseases such as strokes, heart attacks, renal failure, and diabetes.

The UK urgently needs to strengthen provisions for the storage and use of cord blood stem  
cells. Government should provide assistance to increase the awareness of the value of  
umbilical cord blood for the treatment of diseases and for further research of new treatment  
methods.

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## (2) Background to the Legislation

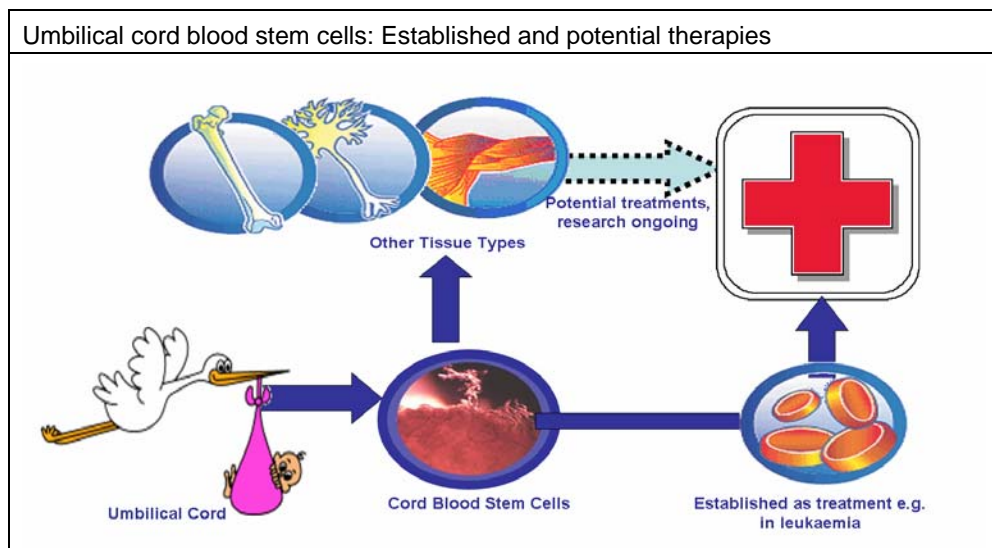
Adult stem cells in the bone marrow are used to treat many severe diseases including leukaemia. Today most bone marrow transplants are from a family member, because the risk of immune rejection is very great. There are more than 24,000 cases of leukaemia in the UK per year. 50% of patients who need a bone marrow transplant in the UK are unable to find a matched donor.

Cord blood stem cells do not require as close tissue matching as bone marrow.

Cord Blood Stem Cells are present in the blood of the umbilical cord linking the child to the mother's placenta. This blood can be collected from the cord after birth with no harm to the mother or the child.

Cord blood stem cells are not just an alternative to bone marrow stem cells: A team led by NESCI researcher Professor Colin McGuckin demonstrated the existence of pluripotent cells in cord blood, showing that Cord blood-derived cells have the capacity to form different tissue types not dissimilar to embryonic stem cells. They can be differentiated into tissues of endodermal, mesodermal and ectodermal origins including liver, neural, liver, pancreatic, vascular and corneal tissues.

Some applications of cord blood stem cells may simply improve the clinical condition of the patient. For example, preliminary clinical trials in juvenile diabetes have shown that cord blood cells do not 'cure diabetes' but cause a reduction in the daily insulin dose that needs to be injected.



Over 10 000 cord blood transplants have been performed to date. In Japan, 50% of stem cell transplants between unrelated individuals now use cord blood. Globally, over 300 000 cord blood samples have been stored and are available for use in a way similar to bone marrow through international registries.

Current coverage, however, is insufficient to meet demand. In the UK, provisions for cord blood storage are severely lagging behind other European countries. Only a handful of hospitals collect cord blood for the public bank. Under the public system parents altruistically donate umbilical cord blood at birth for storage in case a tissue matched patient, usually a child, requires a stem cell transplant. Cord blood can also be banked privately, but not all private banks operate to high ethical and scientific standards.

### (3) The Amendment

The 1990 Act makes no express provision for cord blood cells. This will not be changed by the current Bill.

A new clause amendment tabled by Robert Key (with David Burrowes, Mark Durkan, Andrew Dismore, David Taylor, Lee Scott, MP's in support) to strengthen the provision of cord blood facilities and cord blood science in the UK.

"To move the following Clause:—

'(1) It shall be the duty of the Secretary of State to—

- (a) encourage women to donate their umbilical cord blood after birth;
- (b) increase the awareness of the value of umbilical cord blood for the treatment of diseases and for further research of new treatment methods; using cord blood stem cells;
- (c) promote the collection of cord blood from specific shortage groups, including minority groups including mixed race families where there is a history of diseases, treatable by cord blood.

(2) It shall be a requirement for doctors to inform pregnant women of the benefits of collection and storage of cord blood.'

There are some slight concerns with this amendment:

**Regulatory:** It is not clear whether this amendment would be a suitable provision in an Act that regulates Fertility and Embryology. The competent Authority for regulatory affairs under the Act is the HFEA. However, it is clear that cord blood procurement, and storage is regulated by the Human Tissue Act 2004 and therefore fall under the auspices of the Human Tissue Authority (HTA). Recently, the HTA has lifted a moratorium the requirement for cord blood collection sites to be licensed. Many sites may not be able to afford a license without extra support.

**Practical:** It is not clear if the costs for providing cord blood services under this provision would fall to individual maternity centres. The collection of cord blood and attendant administrative procedures place a burden on the midwife at a particularly busy and risky time, especially against the background of staffing shortages within the National Health Service. One should not, if at all possible, demand extra work from healthcare professionals without providing specific structural and financial assistance.

**Jurisprudential:** Section (2) may be perceived as overly prescriptive. While cord blood collection may have great benefits in many cases, this will not be universally the case. It is important that cord blood stem cells are not hyped as a 'wonder cure' and that doctors retain the discretion to inform their patients as they deem appropriate in individual circumstances. However, in general, it would be helpful if doctors were provided with information that they can pass on to patients.

**Despite these reservations, the essence of the Amendment is to be welcomed.**

If those or broadly similar provisions became law, this would represent a significant step forward for stem cell science in the UK. We urge Members of Parliament to give serious consideration to strengthen cord blood stem cell science in the UK.

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#### **(4) Further information**

This brief has aimed at presenting the perspective of scientists and clinicians on the proposed legislation in a succinct and simple manner.

We would greatly welcome a chance to explain the underlying science and the therapeutic potential in greater detail. Please do not hesitate to contact us with any further questions or comments.

The North-East England Stem Cell Institute, a collaboration between the Universities of Durham and Newcastle, the Newcastle upon Tyne Hospitals NHS Foundation Trust and other regional partners.

To arrange a meeting with NESCI researchers or to learn more about stem cell science in the North East please contact:

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