Original Article

Umbilical cord blood banks: Modern day alchemy

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ABSTRACT Stem cells are at the forefront of hopes for developing treatments for a range of serious diseases. The sources of those stem cells can be controversial, particularly for embryonic stem cell lines. Increasingly parents are opting to collect umbilical cord blood shortly after delivery of the baby, some to satisfy a current treatment need for stem cells and others to 'future-proof' their families and themselves against possible disease and preserving for themselves a potentially potent resource for future regenerative treatments. The author reviews recent and forthcoming changes in regulation of this area, potential legal problems and the implications of compliance for biotech companies within the field or who have current treatments which may benefit from collaboration with those who are in the field. The paper looks at, in particular, the legal position in the UK, and issues relating to, for example, ownership of cord blood deposits and anonymity of deposits.

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INTRODUCTION

Research and development of new stem cell therapies will be of interest to many businesses operating in the arena of treatment of human diseases and conditions. Stem cell treatments have been lauded in the media as the means to reach the Holy Grail of cure for certain debilitating diseases, with the potential to render pharmacological treatment of such diseases and conditions obsolete. What is more likely is that stem cells will lead the way in new areas of development and refinement of pharmacological treatments – moving away from palliative care and into treatments which

assist or trigger the body to repair damaged tissue itself. Proper, transparent and openminded regulation of this area is essential to ensure ethical research leading to safe stem cell therapies for clinical trial. In the UK, regulation of this area by the Human Tissue Authority ('HTA') and the Medicines and Healthcare products Regulatory Agency ('MHRA') under a variety of legislation¹ (see Figure 1), including the new Human Fertilisation and Embryology Bill, seems set to guarantee the UK's place at the forefront of research and development in this arena. The operation of the public and private umbilical cord blood banks, within the UK regulatory framework, looks set to provide researchers and clinicians with an ethically sound and potentially plentiful supply of stem cells for

Correspondence: Helen Smith K&L Gates, 110 Cannon Street, London EC4N 6AR, UK E-mail: helen.smith@klgates.com research and treatment, turning what was once seen as a waste product into a valuable resource. Table 1 sets out a history of some of the most significant advances in stem cell research.

Stem cells are at the forefront of hopes for future medical treatments for a range of debilitating and life threatening human conditions. The use, and more particularly the sources, of stem cells for research and therapies remain fraught with ethical and legal difficulties. Umbilical cord blood collection

and long-term storage is an increasingly popular means of obtaining stem cells, including for individual families with a current need for treatment and for those hoping to 'future proof' themselves against their family developing serious diseases which may be treated with stem cells. It is an area in need of, and attracting, increasing levels of regulation. This paper outlines the current regulatory framework in the UK, including the recent votes on the Human Fertilisation and Embryology Bill making its way through

Human Fertilisation and Embryology Authority

If involving embryonic stem cells, the Human Fertilisation and Embryology Authority ("HFEA"), acting under the HFE Act 1990, (due to be updated and amended by the HFE Bill in 2008/2009) regulates procurement of gametes and the associated processing involved in creation of embryos. The HFEA also oversees the use of embryos in derivation of stem cell lines, but is not involved in regulation of stem cell lines themselves. (Once the human embryonic stem cell line is fully characterised and cultured to ensure uniformity, it is a condition of all HFEA research licences that the cell line is deposited in the UK Stem Cell Bank.)



Point at which cell line derivation processing where the embryo is dissociated that the HFEA's regulatory remit ends and the HTA's begins.

Human Tissue Authority

The Human Tissues Authority ("HTA") acting under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, (which enacts the EU Human Tissues and Cells Directive) regulates procurement (re non-embryonic stem cells), testing, processing, storage, distribution and import/export of stem cell lines for human application. The HTA is also responsible for approving transplantation of organs and bone marrow fron living donors. If a product containing human tissue or cells is not considered (by the MHRA or EMEA) to be a medicinal product or investigational medicinal product then it will fall to be considered only by the HTA under the Quality and Safety Regulations.



Products classified as medicinal products or investigational medicinal products are regulated by the HTA only as far as procurement and testing of human tissues and cells is concerned. Such products thereafter fall within the regulatory remit of the MHRA.

Medicines and Healthcare products Regulatory Agency

Once a Master Cell Bank (as defined in the EU Guidance on Good Manufacturing Practice 2007) is created with a reasonable expectation of clinical utility in a medicinal product, it will fall within the remit of the Medicines and Healthcare products Regulatory Agency ("MHRA"). There is currently no specific regulatory framework/legislation in place in the UK which applies to stem cell therapies or products. From December 2008 the MHRA, and the European Medicines Agency ("EMEA"), will be working under the EU Advanced Therapies Regulation (2007/1394EC) which lays down specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products including those arising from stem cells. Unless exempt, advanced medicinal therapies will then require a marketing authorisation granted by the European Commission, for whichthe EMEA will co-ordinate the application and assessment procedures and post-authorisation supervision.

Figure 1: Flow chart of current regulation of stem cells for human application.

Table 1: Progress in stem cell research

| Date | Event | |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1956 | First successful bone marrow transplant (related donor) for cancer treatment (New York, USA) | |
| 1978 | First IVF baby born (UK) | |
| 1981 | Mouse embryonic stem cells isolated and grown in culture (Cambridge, UK and California, USA) | |
| 1988 | First umbilical cord blood transplant | |
| 1990 | UK's Human Fertilisation and Embryology Act passed | |
| 1995 | Isolation of primate embryonic stem cells (University of Wisconsin) | |
| 1996 | First cloned mammal, Dolly the sheep, born (Edinburgh, UK, using cell nuclear replacement technique) | |
| 1998 | Researchers isolate and grow human embryonic stem cells from blastocysts (University of Wisconsin) | |
| 2003 | First UK human embryonic stem cell line established (King's College London, UK). Human/rabbit admixed embryos created (Shanghai Second Medical University, China) | |
| 2005 | UK Stem Cell Initiative established by UK Government | |
| July 2007 | UK enacts Regulations implementing the EU Human Tissues and Cells Directive | |
| April 2008 | The UK Human Tissue Authority publishes new regulations on collection of umbilical cord blood (pursuant to the EU Human Tissues and Cells Directive) | |
| May 2008 | Already passed by the House of Lords, the Human Fertilisation and Embryology Bill is introduced into the House of Commons in February 2008. Several controversial provisions, including allowing creation of human/animal admixed embryos and screening of embryos for 'saviour siblings' prior to implantation, subject to a free vote in May 2008. MPs vote in favour of allowing those provisions and passing the legislation (expected to come into force late 2008/early 2009). | |
| December | EU Directive on Advanced Therapy Medicinal Products Regulations will apply from 30 December 2008 (it entered into | |
| 2008 | force in December 2007 and is currently undergoing public consultation, contributions due by 10 June 2008 – http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/index.htm) | |

the English Parliament, proposals for future regulation and issues relating to, for example, ownership of cord blood deposits and related privacy issues.

USES FOR STEM CELLS

Stem cells have long been hailed as the new miracle cure for mankind's ageing and ailments. It is frequently unclear what diseases are actually already being treated with stem cells and what 'cures' remain the speculation of scientists, journalists and politicians. Perhaps the most widely known current therapeutic use of stem cells is the bone marrow transplant to treat leukaemia and other types of cancer and blood disorders (including sickle cell anaemia). These types of diseases are also currently treated with peripheral (adult) blood and umbilical cord blood stem cell transplants.² Umbilical cord transplants have recently been reported as more successful at treating childhood leukaemia than the (standard) treatment of bone marrow replacement.³

Areas where adult stem cell transplants have had some anecdotal or limited clinical trial

success in humans and/or success in preclinical trials in animal models, but which lack sufficient verifiable human clinical trial data, include treatment of various neurological conditions, heart disease, spinal injuries and certain autoimmune diseases. Stem cells present hope for improved treatments and potentially cures (by transplantation and/or by research discovering and replicating the factors released by stem cells in repairing and regenerating cells) for diseases as diverse as Parkinson's, osteoporosis, Alzheimer's, Type I Diabetes and Motor Neurone Disease.4 Whether by means of stem cell transplant or by improved medication arising from stem cell research, generally available stem cell-based therapies and cures for these diseases remain some way off.

'Stem cells' is a term used to describe undifferentiated cells which are capable of indefinite self-renewal and have the *potential* to form other cells (see Table 2). Stem cells are medically valuable because of their ability to generate production of new cells, and in the case of pluripotent and to a lesser extent multipotent stem cells, to differentiate into

Table 2: Stem cells simplified

| Туре | Characteristics | Current medical uses |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Embryonic | Usually extracted, soon after fertilisation, from surplus embryos created in fertility treatment. These cells are 'pluripotent', that is, they have the potential to differentiate into every cell type in the body (depending on the stimuli/ triggers to which they are exposed). Particularly valuable in research and treatment as they provide useful information on, among other things, what triggers cells to form a particular type; how generation of new cells is controlled; how the body can repair itself; and why it may fail to do so. Subject to controversy due to ethical/moral objections relating to use of human embryos to create stem cell lines. | Some 'ad hoc' uses in a number of countries of embryonic stem cell transplants to treat a range of diseases/conditions. Some clinical trials underway/ under development. Poor data, controls and reporting of outcomes further devalues transplants which have taken place to date. |
| Foetal | Derived from 'waste' foetal tissue (miscarriage and termination of pregnancy). Multipotent cells displaying greater plasticity than adult multipotent stem cells. Ethical issues and scarcity indicate limited long-term prospects for research and use. | Trialled as treatment for Parkinson's disease with little success. |
| Umbilical cord blood | Extracted from the umbilical cord shortly after delivery of baby and placenta. Umbilical cord blood contains haemopoietic stem cells (multipotent cells which can give rise to all blood cell types). May also contain mesenchymal stem cells – multipotent cells which can give rise to a range of cell types for various organs, subject of speculation as possible future resource for regenerative treatments, for example, for stroke and heart attack. | Cord blood transplants already used in treatment of a number of blood diseases and cancers. NHS umbilical cord blood bank established in 1996. Various commercial cord blood banks also in existence. Worldwide over 10,000 umbilical cord blood transplants have been performed to date (see Fisk and Atun ¹¹). |
| Adult | May be multipotent or unipotent. Only relatively recently become clear that most, and possibly all adult tissues/ organs contain stem cells. Relatively easily obtained (by biopsy) but frequently less useful for research and treatment since the cells have far greater level of differentiation/lack pluripotency displayed by embryonic cells. | Bone marrow and peripheral blood transplants well known as treatments for various cancers and blood diseases. Already highly successful in treatment of corneal (eye) damage, and reported successes also in relation to Type I Diabetes treatment (using transfusions of stem cells derived from patients own blood). |
| 'Cybrid' (human/animal admixed embryonic) | Embryonic stem cells generated from creation and short-term (maximum 14 days) growth of human—animal admixed embryos (animal egg has nucleus removed and replaced with human skin cell nucleus and exposed to electric current to fuse cytoplasm and nucleus and initiate cell division). Arguably even more controversial than embryonic stem cells due to fears surrounding creation of human/animal 'chimeras'. Provisions allowing for creation of and research with cybrids recently passed in HFE Bill. | Currently intended that cell lines derived from cybrids will remain a research tool, no scope in current UK legislation for direct therapeutic use of cybrid stem cell lines. |
| Induced pluripotent | Recently developed, these are adult stem cells which, by introduction of certain controller genes, can be induced to behave as embryonic cells, that is, to produce a range of cell types (depending on the stimuli to which they are exposed) rather than just producing cells of the tissue type from which the cells are originally derived. | Very recent development and not currently in therapeutic use as these cell lines present a particular risk since induction of pluripotency achieved with a cancer causing gene. Some therapeutic testing in animal models already underway, for example, correction of mouse model sickle cell anaemia using induced pluripotent cells. ⁵ |

many different types of cells. It is currently unclear whether the stem cells themselves promote regeneration or if it is factors released by the transplanted stem cells which are the real source of their regenerative effects.⁴ Stem cells make replacement and repair of damaged cells and organs of the body possible, leading to widespread interest

in these cells as the future of regenerative medicine.

CORD BLOOD BANKS

Since 1996,⁶ the NHS has been banking haemopoietic stem cells (HSCs) from umbilical cord blood. These facilities, which operate within the National Blood Service,

are currently funded by the Department of Health. These banks store mainly 'nondirected' or altruistic donations of cord blood collected from women volunteers at three maternity hospitals in England, currently located at Harrow, Barnet and Luton.⁷ The deposits are made available worldwide for matched patients requiring an HSC transplant. The National Blood Service may also, on a case by case basis, store 'directed' cord blood donations for families with a specific potential clinical need for the blood (that is, family member(s) either diagnosed or at high risk of a disease treatable with HSCs). Family members are much more likely to be matched with one another, hence the importance of directed banking in high risk/current need families.

Currently, there are also a number of commercial cord blood banks.8 These generally operate on the basis of private collection and storage of cord blood for families who are at low risk (that is, they are not known to have a family member with or at risk of developing a disease in which HSC transplant would be helpful or necessary). These facilities are used by parents as a 'future-proofing' or insurance policy against the unlikely possibility that the stem cells will ever be needed by a member of the family and for any yet to be developed emerging therapies and regenerative treatments. Such commercial ventures have, for a number of years, been subject to criticism from bodies such as the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives and the HTA. Particularly as several have indulged in misleading advertising campaigns which suggest the potential need for and usefulness of such 'speculative' bloodbanking is far higher than it actually is. 9 They are also seen as 'preying upon' people at a vulnerable time, during pregnancy, taking advantage of natural solicitousness for their family's health and fostering maternal guilt around the issue.

A new model of bank is now emerging, with Richard Branson's Virgin Health Bank launched in early 2007 in a blaze of publicity. ¹⁰ As part of the deal for its customers, the Virgin model splits cord blood between the donor's (directed) private store (20 per cent), the other 80 per cent enters the publicly available bank, adding to the pool of HSCs available through international donor register networks. This is a positive step, welcomed by many. ¹¹ The Virgin Health Bank is still in its early stages, so the feasibility in terms of quality and usability in the long term is yet to be the subject of significant public studies or reports.

There is a serious shortage of matched HSCs (whether bone marrow or umbilical cord) for transplantation and some argue that the approach of Virgin may be the best means of satisfying that current unmet need for HSCs for treatment. 11 It should be noted that the small amount of blood collected at each delivery does leave the issue that, currently, a single private store of HSCs is likely to be sufficient only to treat a small child. Until cell expansion techniques are perfected the amount of blood deposited, if it is ever used, may not be of sufficient volume to be useful.¹² With an increasing number¹³ of parents opting to privately bank cord blood, there are growing issues around collection which has prompted the UK regulatory authorities to act.

LEGAL ISSUES IN THE UK RELATING TO CORD BLOOD BANKS

Collection

Commercial cord blood banks had, until recently, not been subject to any form of regulation in collection of deposits. 14
Difficulties surrounding collection of cord blood for private storage is an issue which has very recently given rise to new regulation in the UK. Collection for private banks imposes an added pressure on attending maternity staff, at a time when the NHS is suffering serious maternity staff shortages, and, more importantly, at a stage in the mother and

newborn's life which is particularly fragile and requires the full attention of those attending. It appears that cord blood for private banking has been collected by untrained individuals, in some cases the newborn's father.

Cord blood should (as is the case with the NHS bank) be collected by trained individuals to avoid pitfalls including inadequacy of sample size, bacterial contamination, inadequacy of maternal consent to the collection and subsequent use and to prevent attention of carers being drawn away from the mother and child in the critical moments following delivery. There is also the risk to the health of the newborn, currently little is known about this but clamping the cord too early may well prevent valuable blood reaching the newborn. There are also issues around correct labelling and identifying of samples.⁶ These issues prompted the HTA to issue on 30th April, 2008 new rules for cord blood collection.

The new rules, ¹⁵ designed to address the issues outlined above, require that all maternity units collecting cord blood must act under an HTA licence, to be applied for by 5th July, 2008, which will ensure that staff have training in collecting cord blood, procedures to ensure medical attention is not drawn away from mother and child and systems to ensure the cord blood cells are traceable from collection through to their use in treatments. ¹⁶ The new regulations have been warmly welcomed by various groups, including the Royal College of Obstetricians and Gynaecologists. ¹⁷

Storage continuity

Another area of serious concern around operation of private banks is the risk of bankruptcy/ceasing to trade. What happens to the collected samples in the event of the bank's collapse? The European Commission has looked at this risk and recommends that insurance be in place to guarantee continuity of storage and transfer of samples to another bank.¹⁸ It appears that many of

the private banks have taken on board this concern, and have in place insurance policies to cover discontinuance of business, but this remains an area of vulnerability for customers. Even with insurance, there is no guarantee for customers of private banks that the stored cells will be available to them in a usable long-term form and there is still no 'guarantor of last resort' for private bank deposits.¹¹

Ownership of deposits

Another area of controversy is the question of ownership of the umbilical cord blood. It has been argued that, under US law, the umbilical cord blood properly belongs to the child (being developmentally, biologically and genetically part of the child).² In this model, the mother has the right and the responsibility to make decisions, consistent with the child's best interest, on whether the blood is collected, and the uses to which the collected blood is put. The alternative, and potentially the view to be favoured under English law, is that once the cord is cut (the placenta remaining within the mother until its subsequent delivery and blood being extracted from the maternal side of the cord clamp), all aspects of the afterbirth are legally hers.⁶ Depending on the terms on which the mother banks the blood, once the blood is collected and stored it may be that the mother gifts it to the child, with the blood held on trust for the child until he/she reaches the age of majority. The trustee, usually the mother, will then be responsible for ensuring the blood is, if used, dealt with in the child's best interests.

A further factor determining ownership is the terms on which the private bank operates and the terms of the contract between the bank and the mother (whether entered into on her own behalf or on behalf of the child). In the case of public banks, the donation is made outright in the best interests of the society of which the mother and child are a part (hence, by extension, there should be no issue over an altruistic donation consented to

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by the mother even if the child were held to be the legal owner of the blood).⁶ Some private banks may impose terms under which ownership of the blood apparently passes to the bank, particularly in the event that ongoing storage fees are not paid.² In the event of failing to pay the fees, it can be unclear whether the parent (either on her own behalf, or on behalf of the child) can insist upon destruction of the blood sample. This leads into a very difficult area because private directed deposits are, by definition, not anonymous and contain (potentially or actually, as a result of genetic and other screening) huge amounts of medical information about the child and, in some cases, also the mother.

Donor privacy

Privacy has the potential to be the greatest concern of all in the commercial banking arena. A huge amount of medical information on the child can or will be, through genetic and other screening, potentially available and (in the commercial bank) inevitably will be linked to the identified child to whom the deposit relates. Loss or misuse of this information could be devastating to the child's rights to private and family life. 19 There have already been a number of high-profile losses of sensitive personal data recently admitted by the UK government, 20 leading one to wonder how many commercial organisations have been guilty of similar faults but have not seen fit to admit their mistakes.²¹ The risk for this sort of data loss in the digital age must be considered significant and especially dangerous when it concerns such potentially extensive medical information on identifiable children.²²

THE FUTURE

Although still some years off, it now seems almost certain that stem cells will be central to development of treatment and possibly even cure of some of the most debilitating of human diseases and conditions. The race is on to find reliable and ethically neutral means of generating

usable multipotent cells, and for establishing, through research and clinical trials using these cells, revolutionary new drugs and 'transplants' to treat our worst ailments. A continued debate in this area is whether to continue research to find out more about the properties of stem cells or to go straight for therapeutic uses while knowing nothing about the potential long-term consequences of such use.⁴

Reputable commercial banks collecting deposits of UK cord blood are currently subject to HTA licences and MHRA accreditation and comply with the various UK and EU regulations applicable. Researchers in this area are also governed by a range of legislation, and they fall within the remit of the HTA which licences research and therapy using human-derived tissues and cells. Failure to obtain a licence from the HTA, or the MHRA,²³ for work in this area may result in criminal conviction, with the imposition of an unlimited fine and/or up to two years imprisonment. See flow chart in Figure 1 summarising the UK regulatory framework.

FINAL THOUGHTS

The English Human Fertilisation and Embryology Bill ('the Bill') has recently (May 2008) been the subject of free votes in the House of Commons. In the two weeks before writing this article, the Commons passed provisions allowing (licensed) creation and use of human admixed embryos²⁴ (see Table 2) and the ability to screen and select 'saviour sibling' embryos for implantation.²⁵ Requirements for consent in the Bill which would have created great difficulty for stem cell research into childhood genetic diseases, where the child is likely to die before reaching the age of majority, were dropped.²⁶ The passing of these aspects of the Bill are to be welcomed as they help secure the UK's future as a country in which leading stem cell research can be undertaken legally and with adequate regulation overseen by the HTA and MHRA.

The Department of Health is, at the time of writing, undertaking a review of umbilical cord blood collection, storage and use. The review, carried out by Technopolis Limited, was due to prepare an initial report on the current use of stem cells collected at birth, to be presented to an expert workshop on 28th May, 2008. The workshop was due to include representatives from government departments, regulatory agencies, research councils, public and private blood banks and the Royal Colleges. Two international cord blood research experts, Professor Colin McGuckin (University of Newcastle) and Albert Bekassy (Lund University Sweden), were also due to attend. The workshop's aims are stated to include assessing current policies, practices, spending and service provision for the collection, storage and use of umbilical cord blood stem cells in the National Health Service and private sector in the UK, and looking at similar issues in the United States, Canada, Japan, France and China.²⁷ We await the results of that workshop, and any consequent policy or regulatory changes with interest.²⁸

REFERENCES AND NOTES

- The legislation which applies is the Human Tissues Act 2004, the UK Quality and Safety Regulations 2007 (implementing the EU Tissues and Cells Directive 2004/23/EC), the EU Blood Directive 2002/98/EC (administered by the Medicines and Healthcare products Regulatory Agency) and Europe-wide Advanced Therapy Medicinal Products Regulations (administered by the European Medicines Agency).
- Perhaps more properly referred to as transfusion rather than transplant. See Annas, G. J. (1993) Waste and longing – The legal status of placental-blood banking. New England Journal Medicine 340(19): 1521–1524.
- News article Umbilical cord best treatment for childhood leukaemia, *The Guardian*, 8 June 2007, http://www.guardian.co.uk/society/2007/jun/08/ health.medicineandhealth1.
- 4. Medical uses of Stem Cells: http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Human-Fertilisation-and-Embryology-Bill/Stem-cell-basics/WTD040067.htm.

- Hanna, J. et al. (2007) Treatment of sickle cell anaemia mouse model with iPS cells generated from autologous skin. Science 318: 1920–1923.
- Royal College of Obstetricians and Gynaecologists, Scientific Advisory Committee Opinion Paper 2, Umbilical Cord Blood Banking, June 2006.
- 7. These three locations were chosen on the grounds of the mixed ethnicity of the local populations in an attempt to compensate for the ongoing shortage of bone marrow donors from minority groups (of particular relevance in the context of sickle cell anaemia). The Anthony Nolan Trust Cord Blood Bank launched in September 2008, creates a further public bank, with a special facility in Nottingham to store cord blood collected from births at King's College Hospital, London. The Nottingham facility is unique in being associated with a research institute. See http://news.bbc.co.uk/1/hi/health/7608655.stm.
- 8. More than 10 providers in the UK to date, to whom patients pay fees (of one to several thousands pounds) for a facility they will probably never use (see *Fisk* and Atun¹¹ below).
- 9. Estimates for the chances of an individual in a family with no history of blood disease making use of personal cord blood before the age of 20 are low, possibly approaching zero, for example, in the region of 1 in 20,000. Additionally, when HSCs are used, autologous (self) stem cell transfusions are also likely to be less useful than non-self (and therefore 'non-diseased') transfusions, see Annas².
- Mayor, S. (2007) World's first public private cordblood bank launched in UK. BMJ 334: 277.
- Fisk, N. M. and Atun, R. (2008) Public-private partnership in cord blood banking. BMJ 336: 642–644.
- 12. Although advances have already been made in this field, see for example news article Leukaemia sufferer given bone marrow transplant using umbilical cord blood, *The Independent*, 9 July 2002, http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/leukaemia-sufferer-given-bone-marrow-transplant-using-umbilical-cord-blood-647781.html.
- 13. Although figures still remain very low, in Europe it is estimated that only 0.6 per cent of live births in 2007 gave rise to privately banked cord blood units, see http://www.cryo-save.com/company_news.html?id_news=76.
- 14. The collection of cord blood for *public* banking is carried out by trained National Blood Service staff in aseptic conditions (within the delivery unit but outside the delivery room) immediately after delivery of the placenta, see RCOG Opinion paper ⁶ above.
- 15. Made by the HTA pursuant to the European Union Tissue and Cells Directive.

- Human Tissue Authority. New rules for cord blood collection, http://www.hta.gov.uk/newsroom/ media_releases.cfm?cit_id=418&widCall1=customW idgets.content_view_1&usecache=false, accessed 30 April 2008.
- 17. RCOG statement on the new HTA rules for cord blood collection, http://www.rcog.org.uk/index.asp?PageID=2375.
- 18. The European Commission's Group on Ethics in Science and New Technologies. (2004) *Ethical aspects of umbilical cord blood banking*, http://ec.europa.eu/european_group_ethics/publications/docs/publop19_en.pdf.
- 19. Guaranteed in particular under the European Convention on Human Rights (enacted in the UK under the Human Rights Act 1998 for ensuring compliance by Government bodies, by extension the UK Courts must make decisions consistent with those rights). Other legislation of relevance in this area includes the Data Protection Act, directly enforceable against individuals/private bodies and common law rights of confidence, as well as any express or implied contractual confidentiality obligations on the blood bank.
- For example, the names, addresses plus parents' bank details of almost every child in the UK were recently lost, UK families put on fraud alert, BBC News, 20 November 2007, http://news.bbc.co. uk/1/hi/uk_politics/7103566.stm.
- 21. *More firms 'admit disc failings'*: http://news.bbc.co.uk/ 1/hi/uk_politics/7127951.stm.
- 22. Non-directed (altruistic) deposits in public banks will not suffer the same privacy issues as they are stripped of all data relating to the identity of the donor shortly after deposit.
- For medicinal products and in relation to blood and blood derivative work under the EU Blood Directive EC Directive 2002/98/EC.

- 24. MPs back creation of human-animal embryos: http://www.timesonline.co.uk/tol/news/politics/article3964693.ece and see http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html. Note that admixed embryos must be destroyed 14 days after creation (the time at which the primitive streak forms and the cells differentiate from totipotent into multipotent cells and placental forming cells), the cells cannot be introduced into humans.
- 25. The Human Fertilisation and Embryology Bill allows selection of embryos that are a tissue match for sick siblings (but only where necessary to treat sibling's life threatening condition), MPs reject saviour sibling ban: http://news.bbc.co.uk/1/hi/uk_politics/7409264.stm and see http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology. html.
- 26. The explicit consent provisions would have had the effect of preventing creation of cloned stem cell lines from tissue taken from sick children, *Curbs to be relaxed on stem cell consent*: http://www.timesonline.co.uk/tol/life_and_style/health/article3912880.ece and see http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html.
- 27. Hansard Written Answers, 8 May 2008, Human Umbilical Cord Blood Cells, http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080508/text/80508w0029.htm.
- 28. Since writing this paper, the Umbilical Cord Blood (Donation) Bill received its second reading in the House of Commons on 17th October, 2008. The Bill seeks to increase the supply of cord blood in the United Kingdom by imposing on the Secretary of State a duty to promote cord blood donation and issue guidance to medical practitioners and through target setting.