UMBILICAL CORD BLOOD BANKING AND THE NEXT GENERATION OF HUMAN TISSUE REGULATION: AN AGENDA FOR RESEARCH

The transformation of umbilical cord blood from being a waste product to being a valuable source of stem cells has led to the emergence of significant legal, ethical and social issues. This editorial proposes an agenda for research into the regulation of umbilical cord blood banking which focuses on issues of characterisation, consent, the interplay of public and private services, and the importance of applying property concepts. It concludes by stressing the need for reform to be based on well-informed public debate.

INTRODUCTION: CORD BLOOD BANKING, FROM “WASTE” TO “WONDER”

Umbilical cord blood has traditionally been treated as a waste product but with the growing scientific understanding of stem cells, it has become a vital source of stem cells for medical treatment. The stem cells derived from umbilical cord blood can be used in haematopoietic stem cell transplantation, which is a curative therapy for many cancers (leukaemia, lymphoma), bone marrow failure syndromes, haemoglobinopathies, immunodeficiencies and inborn errors of metabolism. As the science for stem cell therapies improves, there is also a real potential for umbilical cord blood to be used as part of a regime for emerging regenerative therapies.

When it was discovered that umbilical cord blood provided an accessible source of stem cells, it was hoped that there would be an increase in the number of individuals for whom transplant was an option. The use of umbilical cord blood was also hoped to increase the number of stem cell donors, particularly for ethnic minorities who have traditionally not had as many donor options. As evidence grew that cord blood transplantation was a safe and effective option in both children and adults requiring a haematopoietic stem cell transplantation, the demand for cord blood could only be met by the establishment and maintenance of an effective network of umbilical cord blood banks.

In the last 15 years the establishment of cord blood banks has become an integral part of the cord blood transplant program. Umbilical cord blood banks fall into two categories: government-funded public cord blood banks, which store donated blood for public access; and private cord banks, which will, for a fee, bank an individual’s blood for personal use. Both types of banks exist in Australia. When umbilical cord blood is used to treat a condition in the child from whom the blood originated, it is referred to as autologous treatment. When umbilical cord blood is used to treat a condition in a person other than the donor child, it is referred to as allogenic banking. Ordinarily the public banks carry out allogenic banking and the private banks carry out autologous banking, although there may be occasions (as discussed below) where both types of use are carried out by both types of banks.

This explosion in activity has raised a number of ethical, legal and social concerns about the regulation of umbilical cord blood banking. In 2010 and 2011 the Centre for Values, Ethics and the Law in Medicine of Sydney Medical School and the Centre for Health Governance, Law and Ethics at Sydney Law School held a workshop and a conference, respectively, on the legal, ethical and social dimensions of umbilical cord blood banking. A number of articles in this special issue have arisen...
from that workshop and conference and the authors are all part of the research team or members of the research project’s expert legal panel. This editorial aims to draw the themes from the papers together and propose an agenda for research in this area.

Umbilical cord blood banking is an extremely fertile soil for the examination of numerous issues in the emerging bioeconomy, its concerns being a mix of public and private policy debates, consent and control issues, generational fairness and access to valuable health resources. We believe that the lessons learned from the study of umbilical cord blood banking regulation will also be useful across the whole range of human tissue technologies.

THE CURRENT AUSTRALIAN REGULATORY ENVIRONMENT FOR UMBILICAL CORD BLOOD BANKING: DEBUNKING THE NOTION OF CORD BLOOD BANKING BEING “NON-CONTROVERSIAL”

At present, there is no common law or statute which directly deals with the practice of umbilical cord blood banking. Instead, legal principles have to been drawn out of a myriad of common law and legislative sources and have to be applied by extrapolation and analogy. For example, one would have ordinarily thought that the human tissue legislation of each State and Territory would provide some guidance, given that it regulates living donor donation of regenerative tissue, donation by children and the sale of human tissue. However, the Human Tissue Acts were never intended to cover umbilical cord blood and it is not clear that any of these laws directly regulate umbilical cord blood donation or banking. Indeed, in New South Wales the 2002 Review of the Human Tissue Act 1983 Report concluded that “the status of [cord blood], and rights which can be exercised over [it], are unclear at law”.

Perhaps this lack of direct regulation has resulted from a feeling that umbilical cord blood banking is uncontroversial or lacking in the same moral and ethical quandaries that have plagued embryonic stem cell therapies. Skene tackles this view head on in her article in this special issue, and clearly shows that, while the regulatory concerns are different from those with embryonic stem cells, they still very much exist. She sets out a number of potential areas of conflict and dispute, including issues of consent, information provision, access, research, the rights of children over the umbilical cord blood, public-private banking, conditional donation and quality control. Using her article as a frame of reference, we outline below what we believe are the major issues facing cord blood regulation, and where we believe future research efforts should be devoted.

THE PROBLEMATIC CHARACTERISATION OF UMBILICAL CORD BLOOD DONATION

One of the major issues concerns the question of where umbilical cord blood originates: is it with the mother or the child? Who is the donor? Primarily this issue arises because the law is unclear as to whether the umbilical cord blood is part of the mother or the child. Generally speaking, the law treats the umbilical cord as being part of the mother during pregnancy. For example, in R v King (2003) 59 NSWLR 472, the father of an unborn child attacked the mother after she had refused to have an abortion and caused an abruption of the placenta which killed the fetus in utero. The New South Wales Court of Appeal accepted that the placenta was part of the mother’s body for the purpose of the law of assault occasioning grievous bodily harm, so that damage to it was an assault on the mother. This view could be extrapolated to umbilical cord blood collection so that both the placenta and umbilicus would be viewed as coming “from” the mother’s body and therefore being regulated by her choices.

---


On the other hand, the law also states that any damage to the placenta or umbilicus which causes injury to the child in utero might be considered a cause of death if the child is born alive but then dies from the injury.\textsuperscript{6} This view would arguably sustain the notion of the umbilical cord blood coming from the child. It also has the benefit of being backed by the genetic fact that the umbilicus is genetically identical to the child. But such views also conflict with the fact that the removal of the umbilical cord after birth has never been considered to be an assault on the child, even though the umbilicus is clearly attached to the child’s abdomen.

The problem with these conflicting views is that if umbilical cord blood is not clearly defined as being the tissue of the mother or the child, it will not fit within the definition of regenerative or non-regenerative tissue under the human tissue legislation and it falls into a legal vacuum. Alternatively, if the umbilical cord blood can be said to originate from both the bodies of the mother and the child, we end up with the same result – the Human Tissue Acts have no capacity to recognise such a “dual” donation and remain silent on the practice.

These conflicting views within the common law and the obvious shortfalls in the legislation clearly show that this is an area ripe for investigation. One such investigation comes from the Jordens et al study in this special issue.\textsuperscript{7} Jordens et al examine religious approaches to umbilical cord blood, namely those of experts in Catholic and Anglican doctrines, Judaism, Islam, Hinduism and Buddhism. While each of these traditions has its own approach to questions of reproduction and personhood, none (with the possible exception of Hinduism) view the umbilicus and placenta as having any special moral or spiritual value, apart from the significance given generally to blood. On that count Jordens et al show us that these questions of donor identity will not be resolved by resort to traditional religious conceptions of the identity of pregnant women and the unborn. What is needed is a thorough conceptualisation of the model of tissue donation during and at the end of pregnancy.

\textbf{THE NATURE OF UMBILICAL CORD BLOOD BANKING: PUBLIC, PRIVATE OR HYBRID?}

The article by Jordens et al does demonstrate a religious preference by most religions for public banking over private banking, seemingly because of the perception that public banking advances the public good in ways that private banking does not.\textsuperscript{8} We believe that there are logical reasons for believing that such views would be widespread across Australian society.

Part of this thinking is reflected in a number of scientific and ethical considerations that have been raised against private umbilical cord blood banking. Indeed, there has been significant professional debate regarding whether there is any scientific or clinical rationale for private umbilical cord blood banking, given the extremely low likelihood of a person requiring her or his own stem cells for autologous transplantation later in life (estimates vary from 1/20,000 to 1/200,000).\textsuperscript{9} There has been relatively little public debate in Australia concerning the emergence of private umbilical cord blood banks, the concept of their price regulation, or the honesty of their advertising. Clearly, more needs to be done in this area.

Concerns have been raised that parents are often presented with erroneous or biased information by commercial/private banks about the relative merits of umbilical cord blood banking at a time when they are vulnerable to being coerced and that these banks “sell” possible, rather than real, applications of umbilical cord blood to capitalise on families’ hopes that other stem cell medical applications will

\textsuperscript{6} R v Iby \textit{(2005) 63 NSWLR 278}; R v King \textit{(2003) 59 NSWLR 472}; R v F \textit{(1996) 40 NSWLR 245}.


\textsuperscript{8} Jordens et al, n 7 at 510.

soon be available and overestimate the true likelihood of needing stored umbilical cord blood.\(^\text{10}\) There is currently no evidence that private cord blood banks have engaged in any form of misleading or deceptive conduct in relation to their services and the possibilities of usage of umbilical cord blood in the future. There is potential in Australia to use the Australian Consumer Law to impose controls on advertising by umbilical cord blood banks but what is first needed is an examination of Australian practice to determine authoritatively if any of the objections raised in other jurisdictions have any merit or application for Australia.

O’Connor et al’s article, the third in this special issue, raises a deeper and more fundamental concern with the current use of the public-private dichotomy in umbilical cord blood banking.\(^\text{11}\) It argues that the line between public and private banking is becoming increasingly blurred by pressure from the private market and the public sector which is forcing both private and public banks to partially adopt the other’s practices. These new hybrid models of banking challenge the very nature of the public-private dichotomy and require us to rethink oppositional positions, particularly those taken against private banking. To that extent, the regulation of public and private banks also needs to be re-examined in light of the fact that the dichotomy is not as clear-cut as it previously appeared.

**CONSENT FROM WHOM, BY WHOM?**

An issue related to the problem of characterisation is the difficulty of identifying who should be the person responsible for giving consent as well as the conditions under which consent should be obtained. If umbilical cord blood is considered to originate from the mother, decisions regarding its collection must be made by the mother and must be based on informed consent. While this would seem uncontroversial on its face, concerns regarding the validity of any consent to donate umbilical cord blood during pregnancy and childbirth have been the focus of intense scrutiny.\(^\text{12}\) Alternatively, if umbilical cord blood is considered to be coming from the child, there is the added difficulty that parents must exercise their parental power to consent to donation on the child’s behalf. In doing so, the law would arguably require them to act in the child’s best interests. If this model were correct, both the mother and the father would have equal rights to consent to the donation and storage. A number of issues then become apparent, such as whether the consent of both parents is required and what should happen when the mother and father disagree about whether the umbilical cord blood should be donated and stored. A further complication arises in private umbilical cord blood banking where services are often pitched at third parties to the birth, namely grandparents.\(^\text{13}\) If the grandparent is paying for the procedure, what say (if any) does he or she have in the banking?

**THE PROBLEM OF PROPERTY RIGHTS**

The use of umbilical cord blood both therapeutically and in research has necessitated a re-evaluation of the ownership of this tissue in both ethical and legal terms. The discussion regarding whether cord blood is part of the mother’s body or the child’s is fundamentally a search for origins as a means of establishing a kind of “ownership”. This is very similar to the logic of “first possessor” claims where a person argues that they own something because they possessed it first. In contrast, an early study of umbilical cord blood collection suggested that cord blood should have the same status as any donated


\(^{13}\) See eg the website of Cell Care Australia which advertises the “gift” of cord blood banking for grandparents: “Cord blood banking with Cell Care makes a wonderful gift – it’s a lasting insurance policy that will give the baby’s parents peace of mind for years to come. Few other gifts can match this.” See Cell Care, Cord Blood as a Gift, http://www.cellcareaustralia.com/get-started/cord-blood-as-a-gift.aspx viewed 23 January 2012.
organ or tissue, by which it was meant that it should be treated as being owned by the child, and this concept has since become broadly accepted in many countries.\textsuperscript{14}

The difficulty with applying this type of property language to umbilical cord blood is that the common law has traditionally viewed human tissue as a res nullius, meaning tissue was a thing that could not be owned by anyone.\textsuperscript{15} Skene has argued that the res nullius rule is based on a number of ethical, social and political factors:\textsuperscript{16}

The reasons may be emotional (a repugnance at people selling their bodies and body parts); familial (stored genetic material should be available to blood relatives for their own testing, not subject to veto by one person); pragmatic (the possible consequences of such a principle for hospitals and laboratories …); economic (undue fettering of teaching, research; commercialisation of biological inventions); and social (maintenance of museum collections).

A longstanding exception has existed for tissue which has been laboured upon using work and skill. This was recognised by the High Court in \textit{Doodeward v Spence} (1908) 6 CLR 406, a case involving the preservation of a two-headed stillborn fetus in a jar.\textsuperscript{17} Griffiths CJ, who gave the clearest exposition on the exception, stated (at 414):

By whatever name the right is called, I think it exists, and that, so far as it constitutes property, a human body, or a portion of a human body, is capable by law of becoming the subject of property. It is not necessary to give an exhaustive enumeration of the circumstances under which such a right may be acquired, but I entertain no doubt that, when a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it, at least as against any person not entitled to have it delivered to him for the purpose of burial, but subject, of course, to any positive law which forbids its retention under the particular circumstances.

In the umbilical cord blood context, the work and skill exception allows for property rights to cord blood. It seems more than arguable that the cryo-preservation of the cord blood would satisfy the threshold for work and skill. Interestingly, the work and skill exception, in the context of public banking, would grant the property rights to the person responsible for the preservation of the tissue (ie the bank), and not to the donor. In private banks it would give the ownership rights to whoever paid for the labour, which in many cases will be one or both parents, but may also involve a third party, such as a grandparent.

Recently, there have been developments which have raised the potential for further exceptions to the res nullius rule. As Ball has forcefully argued,\textsuperscript{18} Griffiths CJ had no intention in his judgment in \textit{Doodeward} to create a sole and exclusive exception, and while it may have taken a long time, English and Australian courts have now accepted the existence of property rights in human tissue which has not been subject to work and skill. In \textit{Yearworth v North Bristol NHS Trust} [2010] QB 1 a number of

14 Sugarman et al, n 10.


17 Other examples of cases adopting this work and skill exception include \textit{R v Kelly} [1999] QB 621 and \textit{Dobson v North Tyneside Health Authority} [1997] 1 WLR 596.

18 Ball, n 15.
male patients sued for the loss of sperm that had been negligently stored during their cancer treatments. Lord Judge CJ gave the opinion of the Court of Appeal that it was time to recognise property rights beyond the narrow confines of the work and skill exception (at [45]):

[W]e are not content to see the common law in this area founded upon the principle in Doodeward ..., which was devised as an exception to a principle, itself of exceptional character, relating to the ownership of a human corpse. Such ancestry does not commend it as a solid foundation. Moreover a distinction between the capacity to own body parts or products which have, and which have not, been subject to the exercise of work or skill is not entirely logical. Why, for example, should the surgeon presented with a part of the body, for example, a finger which has been amputated in a factory accident, with a view to re-attaching it to the injured hand, but who carelessly damages it before starting the necessary medical procedures, be able to escape liability on the footing that the body part had not been subject to the exercise of work or skill which had changed its attributes?

The court acknowledged that the sperm had come from the men and that the men still retained the power to control decisions concerning its usage. On that basis, the court found that the donors had maintained a form of ownership. The separation of the ownership of the sperm (the donors) from possession of the sperm (it being stored in the hospital) had given rise to a gratuitous bailment which was breached by the NHS Trust through its negligent destruction of the sperm.

As Skene points out, the decision in Yearworth has now been accepted as good authority by two Australian courts in Bazley v Wesley Monash IVF Pty Ltd [2010] QSC 118 and Re Edwards (2011) 4 ASTLR 392; [2011] NSWSC 478. These decisions make clear that other interests, such as those of the child and perhaps other genetic relatives, may also exist, even when such claimants had not added their work and skill to the tissue.

Given these developments, we would go further than Skene (who argues for a contractual solution) and say that there is no doubt that banked umbilical cord blood has become property.19 The real questions should be about how property laws apply, rather than whether they should or should not. This is an area in which the property “horse” has well and truly bolted. It is time for property lawyers to join the chase and explain how the traditional concepts of gifts, trusts, conditions, assignments and dispositions can be applied to rein the colt in.

Any increase in donor power and control will inevitably raise questions about the limits of that power and control. The article by Komesaroff et al in this special issue examines the problems of conditional donation which is based on racial or ethnic grounds. They argue that, on current evidence, the arguments in favour of allowing such donation are outweighed by its potential detrimental effects.

What effect do these findings have on the emerging property rights in human tissue? If one believes that property rights must necessarily include a right to free alienation, then it might be argued that the power to make racist dispositions is an inevitable consequence. But such logic shows a lack of understanding of the nature of property rights and the fact that the common law has always placed controls of varying degrees on the assignment and disposition of property. Complete freedom of property is a 19th century myth – a powerful myth, but a myth nonetheless.

---

19 Skene, n 5 at 492.
21 We are not the first to argue this. See Munzer SR, “The Special Case of Property Rights in Umbilical Cord Blood for Transplantation” (1999) 51 Rutgers L Rev 493.
There are myriad historical examples of limits to property: the rule of primogeniture;\(^{23}\) the rule against perpetuities;\(^{24}\) the illegality of assignment of public pay;\(^{25}\) the public policy against selling a bare right to litigate;\(^{26}\) the public policy against assignment of contracts for personal services;\(^{27}\) the public policy against illegal and immoral trusts;\(^{28}\) and public policies against gifts which prevent marriage,\(^{29}\) require divorce\(^ {29}\) or require the separation of parent and child.\(^ {31}\) All these rules reflect particular societal concerns which required the common law to place limits on what people could do with their property. While many such rules have come and gone, enough of them remain as useful tools for mapping out the boundaries of the new property in human tissue. It is now up to us to pick up these tools and use them.

**The Way Forward: Regulation Based on Open Public Consultation**

We have argued for a number of specifically targeted areas for future research into umbilical cord blood banking in Australia. Of course, any arguments for change or reform of the current regulatory environment must be undertaken in a targeted and intelligent fashion. Weisbrot's article, the final one in the special issue, is devoted to these issues.\(^ {32}\) Weisbrot draws on the experience of the Australian Law Reform Commission and its report *Essentially Yours: The Protection of Human Genetic Information in Australia*,\(^ {33}\) in looking at the pitfalls of any future reform of umbilical cord blood banking regulation. For Weisbrot, the core issue is to maintain openness and transparency in any regulatory review and to balance that with public education and debate which is informed by valid science. In other jurisdictions where such issues were not carefully balanced, regulatory efforts were stymied by a lack of public faith and trust.

We believe this special issue of the *Journal of Law and Medicine* is an important first step in analysing the problem of Australian umbilical cord blood banking regulation. We hope it will provoke an informed public debate, as described by Weisbrot. We thank all the members of our research team and the participants who came to our workshop and conference. We also would like to give special thanks to Professor Ian Freckelton SC, our illustrious editor, and Susan Tarua of Thomson Reuters, for their kindness and professionalism in bringing this special issue to fruition.

*Cameron Stewart and Ian Kerridge*

---

\(^{23}\) See Buck AR, "‘This Remnant of Feudalism’ Primogeniture and Political Culture in Colonial New South Wales with Some Canadian Comparisons" in McLaren J, Buck AR and Wright N (eds), *Despotic Dominions: Property Rights in British Settler Colonies* (UBC Press, Vancouver, 2005).

\(^{24}\) *Perrot’s Case* (1594) Moo KB 506; 72 ER 634; *Whitby v Mitchell* (1890) 44 Ch D 85; *Nemesis Australia Pty Ltd v Federal Commissioner of Taxation* (2005) 150 FCR 152.

\(^{25}\) *Arbuthnot v Norton* (1846) 18 ER 565.

\(^{26}\) *Prosser v Edmunds* (1835) 160 ER 196; *Fitzroy v Cave* (1905) 2 KB 364; *Glegg v Bromley* (1912) 3 KB 474; *Campbells Cash & Carry Pty Ltd v Fostif Pty Ltd* (2006) 229 CLR 386.

\(^{27}\) *Nokes v Doncaster Amalgamated Collieries Ltd* [1940] AC 1014; *Queensland Insurance Co Ltd v Australian Mutual Fire Insurance Society Ltd* (1941) 41 SR (NSW) 195; *Pacific Brands Sport & Leisure Pty Ltd v Underworks Pty Ltd* (2006) 149 FCR 395.


\(^{29}\) *Church Property Trustees, Diocese of Newcastle v Ebbeck* (1960) 104 CLR 394; *Re Johnson’s Will Trusts* (1967) Ch 387.


\(^{31}\) *Re Boulder* [1922] 1 Ch 75; *Re Piper* [1946] 2 All ER 503; *Penfold v Perpetual Trustee Co Ltd* [2002] NSWSC 648.


\(^{33}\) ALRC, n 15.
Blood cells are vital to the human body. There are three types of blood cells: Red blood cells, which transport oxygen throughout the body. The Council of Europe supports and recommends the development of altruistic and voluntary donation and the public banking of cord blood for allogeneic transplantation. Low, there is a very high probability that, should the donor or a family member (sibling) of the donor need a transplant in the future, the unit would still be available even if it was stored in a public use bank. The banking of cord blood and other tissues can be compared with the production of cell transplants which: Should be sterile. Number of viable cells should be sufficient to restore the hematopoiesis and further functioning of the graft. Should not contain any dangerous cryconservative substances. Accordingly, the relevant national and Continue Reading. Therefore, cord blood banking in all countries is a subject of strict regulation by numerous national and international legal acts. Table 1. Regulation of the banking of the umbilical cord blood, other human tissues and cells in different countries of the world. State. The authority, regulating the banking of the umbilical cord blood, other human tissues and cells. Austria. Bindesministerium fur Gesundheit, Familie, und Jugend. Public Umbilical Cord Blood. Banking and Charitable Trusts. In Imogen. Goold, Kate Greasley, Jonathan Herring, Loane. Skene (Eds.), Persons, Parts and Property: How. Should we Regulate Human Tissue in the 21st. Century? , (pp. 53-65). Umbilical cord blood banking and the next generation of human tissue regulation: An agenda for research. Journal of Law and Medicine. 19(3), 423-429.