Opponents of human embryo research have understandably welcomed pluripotent stem cells being derived from body cells including cells from umbilical cords after childbirth. The cord would otherwise be discarded and embryos are not destroyed. However, there are other ethical, legal and political issues in cord blood collection, whether for the child’s future use, or a public blood bank. Information and consent procedures may be misleading. Some parents have false hopes about potential outcomes. The right of access to stored blood and other benefits is sometimes uncertain for children and their families. Private stem cell repositories may compete with public ones. People may want to impose conditions on donation. Quality control may be an issue.

INTRODUCTION

According to the website of Viacord, an organisation based in Massachusetts that collects, processes and stores human cord blood:

*Your baby’s cord blood is a valuable source of non-controversial stem cells; the building blocks of our blood and immune systems. Cord blood stem cells, like bone marrow stem cells, are free of political and ethical debate. The value and benefits of stem cells found in umbilical cord blood are clear; cord blood collection saves lives today and medical researchers are exploring new uses for umbilical cord blood stem cells for tomorrow, including diabetes, heart disease, and stroke.*

Storing your newborn’s cord blood means that should there be a need, your baby will have a source of stem cells that is an exact match, with no risk of rejection. There is also a strong possibility that his/her siblings will be a match as well. This is important because clinical studies demonstrate that stem cell transplants are nearly twice as successful when the stem cells come from a family member rather than from a non-relative (eg, a public bank).1

This article challenges the assumption that the collection, processing and use of cord blood are “non-controversial” and “free of political and ethical debate”. While free of the concerns surrounding the derivation of human embryonic stem cells (hES cells) for research, there are nevertheless significant ethical, legal and political issues relating to human cord blood cells. The article discusses these issues in relation to both “public” and “private” cord blood banks. Public banks are operated by the government to provide cord blood to those who need it for their health care, or for research. Private banks store a child’s own blood for the later use of that child or a sibling or other family member, with collection and storage costs paid by the child’s parents.

MISLEADING INFORMATION AND CONSENT PROCEDURES

It is important for both ethical and legal reasons that parents are properly informed about the collection and storage of cord blood before they consent. Ideally, this information should be provided during pregnancy and not in the delivery room.

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Matters about which parents might expect to be informed include the following:

- the reasons for collecting and storing cord blood, with a realistic description of the potential benefits without exaggeration;
- the availability of public and private cord blood banks and their purpose (this is discussed more fully below);
- potential uses of stored cord blood – either by the baby, family members or the wider community, and the success rates to date of various uses of stored blood;
- how cord blood is collected, when it is collected and by whom;
- any risks associated with the collection of the blood; eg, if collecting cord blood may deprive the newborn baby of blood the baby may need after birth, or distract the nursing staff from attending to the mother and her newborn baby as the placenta is delivered, or in other ways;
- the cost of collecting and storing cord blood if it is stored in a private cord blood bank, noting the costs to be paid by the parents; and the cost of retrieving it if it is later needed for treatment of the baby or a sibling; and
- the parents’ opportunity to ask questions.

The reasons for providing such information are primarily ethical but there may be legal consequences if information is not given, the woman suffers an injury or loss, and she can persuade a court that she would not have agreed to donate the blood if she had been properly informed about the procedure and its implications. It is arguable that liability for negligent failure to inform could arise on the basis of the principles stated in Rogers v Whitaker (1992) 175 CLR 479 and subsequent cases concerning a doctor’s duty to inform patients about “material” risks. Imagine, eg, that the mother was not told that collecting cord blood might distract the nursing staff from attending to the mother and when the cord blood is being collected she suffers a haemorrhage with serious consequences. Here, she might have an action in negligence not only in relation to failure to take reasonable care in providing treatment but also in failing to provide information about potential risks.

**FALSE HOPES ABOUT POTENTIAL OUTCOMES**

There is understandably an emotional appeal for a woman giving birth to be offered a chance to store the child’s cord blood later as “insurance” for the child if the child should later need a transfusion of stem cells matched to that child, or perhaps a sibling. Even if blood is collected in a public repository for donation to others, women may readily consent in their post-delivery joy at having a healthy baby. But some of this enthusiasm to donate may be based on misapprehensions about what cord blood storage can achieve.

An NHMRC-funded project being undertaken by a Sydney group in 2009-2012 has been investigating issues related to cord blood donation. Part of the project involved talking to pregnant women about their attitudes to cord blood donation and another part involved a retrospective survey of women who have given birth in hospital and have been asked to donate cord blood from their newborn child (and also the fathers of those children). In work to date, this project has found that...
almost half of the 1,873 women in the survey believed that they would need cord blood for their child later in life.\textsuperscript{6} In fact, that is unlikely, at least given the state of current knowledge about the use of cord blood cells in treatment.\textsuperscript{7}

The survey also produced some interesting comments from the respondents that should inform the development of policy in relation to the collection and use of cord blood. For example:

- Information about cord blood banking on the internet is available only in English.
- The information is not always clear and uniform.
- Where information is given directly to pregnant women and their partners, there are different ways of providing it; sometimes it is given by obstetricians and midwives; it may be given during pregnancy or during delivery (93% of the women said that cord blood banking and donation should be discussed during pregnancy).
- If cord blood can be successfully used in treatments (or research), why is it not mandatory for it to be collected? As one woman said, “The cord blood is just thrown away … it is wasted”. This reaction may, in turn, place pressure on health carers to collect the blood, which they may not have the resources to do (in Australia, cord blood is collected in only 1% of births). Public cord blood banks are funded only to collect a limited number of samples and therefore restrict the advertising of their activities to control the demand. Mothers who want to donate and cannot because there are no facilities available are sometimes cross and this may impair the reputation of the cord blood bank.

**Uncertainty about access and other benefits for donors and their children**

If parents have stored their child’s blood in a private blood bank, they expect that it will be available for them to use for their child, or another family member if that should be necessary, and they probably have a legal right to have the blood provided to them. This assumes that the initial arrangements for the deposit of the blood could be construed as conferring such a right; the parents have paid the agreed amount and fulfilled other contractual obligations they have undertaken in their arrangements with the blood bank; and it is physically possible to provide the blood in the circumstances. Such a right would be based on the initial contract between the parties and the parents would have the right to have the blood provided to them, or to be compensated if that is not possible.

Alternatively, the parents might have similar rights under the law of bailment, by analogy with the case of *Yearworth v North Bristol NHS Trust* [2010] QB 1. In that case, it was held that men who had deposited their semen for freezing before undertaking cancer treatment had, “for the purposes of a claim in negligence”, “ownership of the sperm which they had ejaculated”. The reason was that, when the sperm was deposited, “the sole object … was that, in certain events, it might later be used for their benefit” (at [45](f)). This meant that “modest recovery” could be awarded for “mental distress” against a gratuitous bailee in such circumstances as well as damages in tort (at [59]). This case has been followed by two Australian cases involving the removal of sperm for treatment: *Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 118, in which the Supreme Court of Queensland also applied bailment principles to determine how a semen sample stored shortly before death should be dealt with; and *Re Edwards* (2011) 4 ASTLR 392; [2011] NSWSC 478, in which *Bazley* was followed. However, since the deposit of cord blood in a private bank is a commercial transaction and a substantial payment is made for storing the blood, it would not be necessary to rely on the principle of bailment and it would be possible instead to rely on the contract.

If the cord blood has been donated to a public bank, other issues arise. The parents will not pay anything to have the blood stored and it is expected that they will have no right to use the blood

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\textsuperscript{6} Porter, n 5.

\textsuperscript{7} See Devine, n 2 at 332, text to nn 17-19; at 339, text to nn 68-74. As recently as April 2011, it was reported that “one of the first [clinical trials] to assess the efficacy of cord blood in human disease” was about to begin (for children with cerebral palsy): Hagan K, “Testing Power of Cord Blood”, *The Age* (2 April 2011), p 5, also p 18, [http://www.theage.com.au/national/testing-power-of-cord-blood-20110401-1cruf.html](http://www.theage.com.au/national/testing-power-of-cord-blood-20110401-1cruf.html) viewed 6 February 2012. Cord blood has also been proposed for treating spinal cord injury, diabetes, liver and heart disease (p 5).

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themselves, unless the bank chooses to make the blood available at its discretion. But if regenerative medicine lives up to the claims that have been made about it and there are later opportunities to benefit from the cord blood stored in public banks, should people who donated cord blood to the public bank have priority if they need treatment of that kind?

**USE OF STORED CORD BLOOD IN RESEARCH**

Cord blood banks do not store information primarily for the purpose of research (and so may be said not to be biobanks per se). However, blood may be released for research if it does not meet the criteria for banking and potential clinical use. A separate consent process would then need to be initiated, so that donors would be consenting to the use of the blood in research, rather than to the banking of the blood. Once the blood is available for research, an obligation might arise for the biobank to “feed back” to participants any research results that may be significant to them8 (an obligation that the cord blood bank would not have when simply banking the blood).

The security of samples and the information that may be derived from the samples and the protection of people’s privacy are issues in any tissue repository (biobank). There must be a clear protocol for collection, storage and monitoring of stored samples, including who is able to gain access to them and to use them, and for what purposes; and how they are to be disposed of, if they are no longer needed.

There are also questions about “benefit sharing”, if the research produces results that could benefit the original donors. There are no established legal principles about the right to gain access to samples or benefits and opinions are divided. The Human Genome Organisation (HUGO) Ethics Committee’s *Statement on Benefit Sharing* (April 2000),9 dealing with genetic research rather than tissue repositories for clinical use, emphasised the “common shared interest in the genetic heritage of mankind” and hence recommended not only that people should not be paid for contributing tissue for research, but also that they should not expect any reward or priority in treatment if they agree to participate. At most, if the participants are members of a small group that could especially benefit from the research, justice might require that “benefits could be provided to all members of the group regardless of their participation in the research”.10

Legally, however, it seems clear that people who donate cord blood for research would have no legal right to gain access to the benefits of research that follow from the use of the blood, in the absence of a contractual right to share in the benefits of the research. As the Australian Law Reform Commission (ALRC) said in its report on gene patents,11 specifically referring to the HUGO Statement:

There are several barriers to a research participant [which would seem to include cord blood donors] asserting a legal right to control or share in the benefits of genetic research in Australia … [including]

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10 HUGO Statement, n 9.


Nevertheless, the ALRC suggested the possibility of a contractual right in relation to research participants:

It is possible … for research participants to enter into contractual arrangements with researchers that provide some form of control or benefit, in exchange for participation in a research program.\footnote{ALRC Report 99, n 11 at [3.50]. Note that this refers to research rather than the clinical use of tissue but the principle seems to apply in both cases. The current author has also suggested in another context that a contractual right might arise in some circumstances with regard to “significant findings” of genetic research: Skene, n 8, pp 164-167.}

\textbf{THE CHILD’S RIGHTS IN RELATION TO THE STORED CORD BLOOD}

Although it is the child’s blood that is banked, the consent for collection and storage of the blood is necessarily given by the parents. There may be a question later about the child’s rights in relation to the blood. Should the child be consulted if blood that is stored in a private repository is to be used for any purpose other than the child’s own health care; eg, if it is proposed to use it to treat a sibling, or other close blood relative, or to remove it from storage? Or, if the blood is stored in a public repository, would the child have a legal right to “rescind” the donation of the child’s blood by the parents, once the child has reached the age of majority? (The initial period of storage is 18 years and after that, the blood is presumably removed from storage unless there are arrangements to the contrary.)

\textbf{DIVERSION OF FUNDING FROM PUBLIC TO PRIVATE STEM CELL REPOSITORIES}

There are at least 53 public cord blood banks worldwide holding more than 400,000 cord blood units; and 185 private cord blood banks holding about 800,000 cord blood units.\footnote{Numbers quoted by Jordens C, “Umbilical Cord Blood Banking: Beyond the Public-Private Divide”, paper presented at Workshop on Umbilical Cord Blood, Sydney, 25 February 2011; see also O’Connor MAC, Samuel G, Jordens CFC and Kerridge IH, “Umbilical Cord Blood Banking: Beyond the Public-Private Divide” (2012) 19 JLM 512 (below). See also Devine, n 2 at 338.} Comparing these numbers, one may ask whether the private banks are unfairly reducing the supply of donated cord blood to the public banks and the wider community. Is it “selfish” for couples who can afford it to collect and store their child’s cord blood for the child’s later use, rather than to donate it to a public bank from which it may be given to others, or possibly used in research? Or in wider conceptual terms, is individualism undermining the solidarity of the community that arises from sharing resources?\footnote{Jordens, n 15.} And, if regenerative medicine becomes more successful and is widely publicised, will private banks grow even more rapidly as parents become more aware of the potential advantages of collecting and storing their child’s cord blood for later use?

Some of the concerns we may feel about public versus private cord blood banks may be dispelled or reduced if it becomes possible to donate cord blood to both public and private banks from the same blood collection. It is not possible to do that at present as the amount of blood collected is so small. However, there are some arrangements for “hybrid” collection that enable a public bank to use blood collected for private banking in some circumstances. For example, if a public bank has identified a patient as a match for a cord blood sample held by a private bank, the parents may be offered the opportunity to donate it to the public bank, with a refund for the costs associated with the initial collection and storage of the blood. The private banks might then be seen as subsidising the public ones and they could use this in their marketing strategy.\footnote{Jordens, n 15.}
From a different perspective, one might ask whether public banks should be funded from the public purse at the same level as at present, or at all, when the uses of cord blood are still unclear. The allocation of limited health resources is always contentious. Should funds from the public health budget be spent on one area of health service delivery or another? There are difficult issues with cord blood. It is costly to collect and store cord blood and to date, little cord blood has been used in Australia. The use of cord blood in regenerative medicine in the future is still primarily in the realm of possibility; it is not established. Also, it would be possible for Australians to get cord blood from international repositories. It does not need to be collected and stored here. Given the many other demands on public health funding, is it justifiable to fund cord blood banks in case they are needed in the future?

CONDITIONAL DONATION

There are also issues with regard to conditional donation. Should people be permitted, when donating cord blood, especially to a public bank, to place conditions on the use of their child’s blood; eg, that it should be used for an indigenous person, or should not be used for a gay person?

Komesaroff canvassed the arguments for and against these conditional directed and non-directed gifts at the Workshop on Umbilical Cord Blood in Sydney on 25 February 2011:

- Such gifts should be allowed because people are generally allowed to make their own decisions about their bodies and tissue removed from their bodies; we allow people to put conditions on other gifts; it could increase the donor pool by encouraging people to donate when they might not otherwise do so; and there might then be more blood for groups who may currently not get blood, which would address current biases in cord blood banking without causing harm.

- On the other hand, there is no evidence that permitting conditional donation would increase donations, or make more blood available to under-represented groups; and it could cause harm if people not in under-represented groups were discouraged from donating.\(^{18}\)

Komesaroff said that even if conditional gifts are acceptable in the private banking system, they should not be allowed where the whole society is involved. Conditions based on race are probably irrelevant as the stored cord blood is likely to be given to people of the same race on the basis of tissue matching, even in the absence of any direction to that effect. Ethically, medical factors alone should determine who is given the blood.

QUALITY CONTROL

Quality control is essential if cord blood is used in treatment. This falls within the jurisdiction of the Therapeutic Goods Administration (TGA) in accordance with the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth).\(^{19}\) The new regulatory framework for the manufacture of “biologics” which is administered by the TGA is being amended to include “collections” in the Act and the Regulations. The TGA Compliance Group: Office of Manufacturing Quality audits blood, tissue and cellular therapies. It is centred in Canberra, with offices in Sydney, Melbourne and Adelaide. A cord blood repository would also need to comply with the *Australian Code of Good Manufacturing Practice for Human Blood and Tissues*, Manufacturing Principle (2000) MP 1/1009, and the *International Code Blood Standards and Accreditation*. Haemopoietic progenitor cells from cord blood would have to comply with Therapeutic Goods Order 75 but not currently the New Biological Framework of the TGA (though that may be amended in future). Cord blood cells are included in the New Biological Framework.


CONCLUSION

It can be seen from this brief account of some of the ethical, legal and political issues related to cord blood collection, storage and use that there are many issues that need to be discussed in developing future policy and that it is certainly not the case that this technology is “non-controversial” and “free of political and ethical debate”. We need to clarify the issues and discuss ways to deal with them.