Public-private partnership in cord blood banking

Demand for stem cells from cord blood is greater than supply. **Nicholas Fisk** and **Rifat Atun** examine the potential of Virgin's combination of personal and public banking to increase storage

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

Many countries established altruistic public banks of cord blood in response to the increasing need for haemopoietic stem cells for patients with leukaemia and genetic conditions.¹⁻³ The limited coverage of these banks, together with the future potential for stem cell cures, led to the introduction of private autologous banking of both haemopoietic and mesenchymal stem cells from cord blood. However, many health professionals oppose private banking because of its speculative and commercial nature. Consumers face an array of providers with conflicting information on the usefulness of banked cord blood. We analyse the growing cord blood banking industry in the UK and the potential impact of Virgin Health Bank's novel model that provides blood for both personal use and public banks.

Public banks and unmet need

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 haemopoietic stem cell transplant. 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 (www.bmdw.org). Cord blood does not require as close HLA matching as bone marrow, important for the 15-40% of people who have no suitable match in the marrow registries.

The value of public banks is now well established, with over 10 000 transplants performed to date. Current coverage, however, is insufficient to meet demand, which will be further stretched as transplants are increasingly used in adults.⁴⁻⁵ In the UK, only a handful of hospitals collect cord blood for the public bank, with fewer than 10 000 units stored so far.⁶

Private cord blood banking

Commercial banks offer parents the chance to store their child's cord blood as biological insurance, in case it is needed to treat some future disease in the child or close family member. Their promotional literature stresses the "once in a lifetime opportunity" that may "save his or her life,"⁶⁻⁷ and dwells not only on the risks of childhood leukaemia and the curative role of perfectly matched stem cells but also more speculatively on a vast range of conditions potentially treatable by mesenchymal stem cells including diabetes, cancer, Parkinson's disease, and

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heart disease. The resultant interest from expectant parents is understandable.

The attractive business model for this innovation—customers pay full costs up front (typically £1500; €2000; \$2900) for a 20-25 year service unlikely ever to be used—has encouraged entry of over 10 providers in the UK (data available from authors) in a relatively small market, despite the substantial start-up investment in storage facilities. Although there are no figures available for the UK private sector, the total number of cord blood units banked in Europe in 2007 was estimated at only 120 000 (around 0.6% of the annual live births).⁸ While no systematic studies have explored parental attitudes to private banking, the two main reasons for this poor uptake are likely to be professional opposition and the logistics of collection.

Professional opposition

Expert groups, public authorities, and opinion leaders have almost uniformly opposed private cord blood banking for low risk individuals. Opponents include the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives, and the EU Group on Ethics in Science and New Technologies, and banking has been banned in some countries, including Italy and Dubai.⁶⁻¹⁰ Their arguments include:

- Low chance of a sample being used—estimated at 1:2700 to 1:20 000¹¹⁻¹² (the first cord blood transplant in a low risk child has only just been reported¹³)
- Autologous samples being unlikely to be used in childhood leukaemia, the commonest indication for cord blood transplantation, because they may carry leukaemogenic mutations
- Cord blood containing only enough haemopoietic stem cells to transplant a child
- Only half to a third of samples yielding mesenchymal stem cells¹⁴
- Clinical uses for mesenchymal cells are speculative.⁷

Burden of collection

The collection of cord blood and attendant administrative procedures place a burden on the midwife or obstetrician at a particularly busy and risky time, especially against the background of staffing shortages within the National Health Service.⁹ Only 20% of NHS trusts support collection of cord blood for private storage.¹⁵

Commercial risks

A further risk of private cord blood banking is that the bank might go bankrupt or cease trading. The European Commission's Group on Ethics in Science

and New Technologies highlighted this risk, recommending that, “Given the possibility of termination of business or bankruptcy of a commercial cord blood bank, information should be provided to the customers and insurances should guarantee the continuity of the storage and the transfer of the samples to another bank, or the indemnity of the customers.”¹⁶ The group pointed out that most European countries have no specific legislation on cord blood and questioned the legality of private banks, referring to article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which provides that “the human body and its parts shall not, as such, give rise to financial gain.”¹⁷

Private banks have responded to concerns about quality standards and corporate longevity through insurance and by ensuring that samples meet the regulatory standards for use in the NHS.¹⁸ However, the risk remains real, and in case of corporate failure of a private operator within Europe, no “guarantor of last resort” currently exists.

New model

Virgin Health Bank has differentiated itself from its competitors in four ways: establishing trust, the concept of dual banking, profit sharing with charitable contribution to research, and high profile media coverage with support from key opinion leaders (box).

Establishing trust

Whereas private banks emphasise the risk of childhood leukaemia and the lifesaving role of autologous cord blood, Virgin aligned itself with conventional medical wisdom on the benefits of banking. Its promotional material not only acknowledged that “the chances of a child ever needing his or her own stem cells while they are young are punishingly small” but that children with leukaemia need healthy donated cells—that is, an allogeneic not autologous transplant.¹⁹ Virgin advises parents, “It’s highly unlikely that your baby’s own cord blood stem cells would be suitable to treat blood disorders like childhood leukaemia.”

Dual private-public banking

Whereas private banks store only for private use and

Virgin reshapes the cord blood storage model

JAMES KING-HOLMES/SPL

public banks for public use, Virgin introduced the concept of dual banking: 20% of the sample is stored for private use and 80% for public use. The public portion adds to the pool of stem cells available through international registry networks and is considerably more likely to be used than the privately stored component. The trade-off is the reduced volume in the private component, but this is less important given the shift away from autologous transplants in leukaemia. More importantly, if a donor child or family member needs to use a private cord blood sample, then the paired public component would still be accessible, provided it had not been used. Virgin estimates there is <1% chance of the public component not being available, which seems small in contrast to the risk of wastage from infection, poor collection, laboratory error, or other unexpected events such as fire or freezer malfunction.²⁰

Charitable contribution to research

Virgin Health Bank is owned jointly by Virgin Group and the venture capital firm Merlin Biosciences. The bank charges similar amounts to its competitors for storage. Proceeds from Virgin Group’s half are donated to research to help realise the potential of cord blood stem cells.

High profile

Whereas there is little brand recognition among existing providers, the launch of Virgin Health Bank in February 2007 drew on the high profile Virgin Group, in particular Richard Branson. The widespread media coverage in part reflected the novel public-private partnership model and in part the bank’s commitment to research. Unlike other private providers Virgin has succeeded in engaging opinion leaders in the stem cell community with Professors Proctor and McGuckin from the North East England Stem Cell Institute present at the

Virgin Health Bank’s business model

Billing scheme and price similar to its competitors (£1500 for 20 years). Virgin forwent plans to recoup additional costs of public banking (some providers charge an extra £150 for HLA typing) by charging non-Virgin customers for an HLA matched public sample, partly because of market research suggesting consumer resistance to charging and partly because of concern about the propriety of selling human tissue

Initial target is 4000 stored samples a year, around 0.5% of the UK’s annual 722 000 births. With only 20% of hospitals currently allowing collection, maximal market share for all providers would be 144 000

In terms of engaging midwives and obstetricians, Virgin rejected the US strategy of paying collectors as likely to backfire in the NHS. It also rejected the option of third party collectors, both because of the numbers required for UK-wide coverage (around 3000) and the difficulty getting them accredited in a range of hospitals

launch. An unsigned *Lancet* editorial welcomed what it described as the interesting chord struck in combining altruism with self interest, and berated the NHS and Royal College of Obstetricians and Gynaecologists for failing to embrace the exciting initiative of cord blood banking.²¹

Challenges

In reshaping the cord blood storage model, Virgin has addressed the impasse between parents' desire to store their baby's cord blood for the pipe dream of autologous use and the unmet need for public allogeneic banks. Storage of cord blood in the UK has been inadequate with only around 9000 units stored (compared with the US target of 150 000 units), and the government should welcome this cost neutral addition to public provision. However, having only 80% of the sample available will reduce its usefulness, given that even a full sample typically provides insufficient cells to transplant an adult. Progress on expanding haemopoietic stem cells and double transplants should help reduce this problem.^{4 5}

From the customer's viewpoint, the much smaller volume stored privately could jeopardise the already low chance of isolating mesenchymal stem cells for regenerative applications. However, expansion of mesenchymal stem cells, currently based on plastic adherent culture, seems technology limited rather than volume limited. Given the public component will be available for private use in most cases, this downside to the dual banking approach may be only minimal. Nevertheless, Virgin's service still has many of the core disadvantages of private banking, including the risk of corporate failure (without a guarantor of last resort), low chance of harvesting mesenchymal cells, and the speculative nature of future mesenchymal therapy.

To succeed, Virgin will also need to get the support of midwives and obstetricians because they collect the blood and advise prospective customers. This will require endorsement by opinion leaders and public bodies. The charitable intent and public provision may help overturn entrenched professional opposition to commercial banking.

In addition, the logistics of collection must be streamlined to minimise burden on staff. Public banks have provided staff to collect cord blood ex utero in an adjacent room in compliance with recent recommendations.^{6 22} This is relatively straightforward for existing public banks that collect from only a few hospitals at specified times but is more of a challenge for private banks offering national coverage. One solution would be for Virgin to fund additional round the clock midwife cover, which would be affordable if uptake was at least modest (analysis available from authors on request). This strategy would also help improve the problem of midwife shortages in the NHS that could limit take-up.

Finally, fears about risks of private sector involvement in cord blood banking remain high, given recent high profile corporate failures in other sectors (including a bank of different kind). These need allaying through greater transparency, strict regulation of financial practices to reduce creative accounting, and greater account-

SUMMARY POINTS

Public banks of cord blood have proved valuable for allogeneic transplantation. Cord blood banked privately as biological insurance is unlikely to be used.

Virgin Health Bank has adopted a new model, storing 20% for private use and 80% for public use.

The bank will also support stem cell research.

Logistics of collection remain a barrier to professional and government support.

ability to public sector bodies through an appropriate regulatory framework.

Contributors and sources: NMF is a consultant obstetrician with a clinical and research interest in fetal blood stem cells. He chaired the RCOG scientific advisory committee at the time it produced its 2001 opinion paper on umbilical cord blood banking. RA's multidisciplinary research group collaborates closely with the World Bank and the World Health Organization to explore how contextual and health systems factors influence the uptake and diffusion of complex health innovations and new technologies. The analysis draws on a detailed literature review; search of UK cord blood bank providers websites; interviews with the chief executive officer of Virgin Health Bank; discussions with opinion leaders in stem cell science, obstetrics, haematology, and midwifery; and participation in the appraisal of Virgin's proposal as part of RCOG's scientific advisory committee's recent working group on umbilical cord blood banking. NMF and RA conceived the idea, NMF undertook the literature review and interviews, NMF and RA interpreted the data and jointly wrote and approved the final manuscript. NMF acts as guarantor.

Competing interests: NMF is a director of RevealCyte, a consultant to OrniCyte, and is on the obstetric advisory board of Ferring UK. RA is a director of Visbion in UK and Medixine Oy in Finland.

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