



Minutes – The information available to mothers considering donating their cord

Mark Tami MP
David Burrowes MP
Chris Ruane MP
Paul Goggins MP

Orin Lewis, ACLT
Patrick Ojeer, Sickle Cell Society
Dr Rachel Pawson, NHS Blood and Transplant
Vicky Griffin, NHS Blood and Transplant
Julie Frohlich, Guy's and St Thomas' Trust
Rosemary Exton, RCM
Janet Fyle, RCM
Rebecca Roberts, Cells4Life
Jo Taylor, Cells4Life
Zoë Freeman, Bioindustry Association
Linda Moss, Anthony Nolan
Henny Braund, Anthony Nolan
Paula Claytonsmith, Anthony Nolan
Salmah Mahmood, Anthony Nolan.
Fatma Hatimy, Anthony Nolan
Monica Del Olmo, Anthony Nolan
Dr Paul Veys, Great Ormond Street Hospital

Jessica Ridout, Anthony Nolan
Terie Duffy, Anthony Nolan
Chiara DeBiase, Anthony Nolan
Victoria Moffett, Anthony Nolan
Iana Vidal, Anthony Nolan
Katie Begg, Anthony Nolan
Bob Dalgleish, Fanconi Hope
Laura Machin, Lancaster University
Catherine Simpson, Department of Health
Joanna Tilley, Biovault International
Sarah Bunn, Parliamentary Office of Science and Technology
Alan Clamp, Human Tissue Authority
David Fanthorpe, Future Health Biobank
Tabasum Farzaneh, Future Health Biobank
Stephen Baines, Future Health Biobank

Mark Tami opened the meeting. Presentations were given by

Stephen Baines, Future Health Biobank
Rebecca Roberts, Cells4Life
Dr Rachel Pawson, NHS Cord Blood Bank
Linda Moss, Anthony Nolan

Katie Begg also presented research into the cord blood banking systems in the USA, Spain and Cyprus.

Future Health

Marketing materials are put together in a way that is “decent, honest and truthful.” In 2012 the company introduced a Code of Practice for consistency. This is reviewed on a regular basis by an expert board that includes a medical ethicist. All literature is supported with up to date research and evidence, and no emotive language is used.

Clients receive a variety of materials on a frequent basis once they have made a decision to buy a service. The bank ensures that parents are made aware of the option to bank publicly where this is available. Future Health would like all parents to know that cord blood banking exists, both publicly and privately.

Cells4Life

The default position in the NHS is to discard the cord; there should be a requirement that consent is needed to do this too. The NHS doesn't inform parents that they have an option to bank, whereas the private sector does encourage parents to do some research into the practice, to learn about both public and private banking. Nevertheless, the majority of parents will not receive this information during the course of the mother's care. There has

been a marked increase in enquiries on delayed cord clamping following increased media attention.

All marketing materials are subject to the licensing process and the prescriptive nature of these regulations are becoming normalised throughout the EU. During the consent process parents are asked why they are interested in banking; this is to ascertain motivation and manage expectations if necessary. The legislation governing the practice is explained, as well as the need for a banked unit to meet a high standard for it to be useful in the future.

The information currently available on public and private banking needs to be better explained in general, to separate the myth from reality.

NHS Cord Blood Bank

Expectant mothers have access to information at a range of contact points throughout their care. NHSBT operate extensively in the hospitals they collect in; they have a presence on the ward and at antenatal clinics. Staff explain the rationale behind banking, what the process is, what the NHS uses cord for and the commitment required from mothers. A freephone number is available that puts callers through to staff experienced in collection. They also get information included in their 20 week appointment letter. Staff are present at antenatal classes for three of the six collection centres, so that parents can meet them and ask questions. Staff can meet mothers opting for an elective caesarean and consent them then.

When asked about private banking, mothers are given a leaflet that explains the difference. The consent process complies with HTA regulations and the bank is inspected every two years. Mothers are first given the opportunity to express interest in banking (permits collection, not storage or use). Later a full detailed consent form is completed and kept with the physical notes and in digital format. If the mother comes into the unit late into her pregnancy and wishes to donate, a mini consent for collection is taken and full consent is sought after for storage and use. All donating mothers get a 12 week follow up call to check on health of mother and baby, and answer any questions that they may have.

Linda Moss

Anthony Nolan complies with the appropriate regulations and ensures that mothers are given the information to make an informed decision. Information is understandable and easy to access through posters and leaflets in GP surgeries and hospitals, and on the website where mothers can register their interest and view an animation on how the process works.

There is an issue with the nature of maternity care being that the majority of mothers only visit the hospital rarely; most of their care is provided by the community midwife. Anthony Nolan sends leaflets and expression of interest forms with these midwives, and a sticker can be attached to the mother's notes if she agrees to donate. A letter is also sent with the 20 week scan appointment.

During the consent process, it is checked that mothers have the capacity to consent and that donation does not conflict with her beliefs. The process, purpose and scope of donation are explained as well as the consequences and risks. Mothers are made aware of the availability of private banking. They are also given information about the required blood samples and tests, how the results of these will be communicated, the legislation and their rights. There is time for questions and consent forms are signed in triplicate so that mothers can keep a copy. Linda reiterated that, similarly to the experience of NHSBT, the consent process is not a one-stage event due to the amount of information that is imparted.

General discussion

1. Mark Tami (MT) asked the representatives how they manage the expectations of parents who want to bank their baby's cord.

Linda Moss (LM) said that Anthony Nolan explains in its marketing literature that cord blood can be used to treat leukaemia and other blood cancers. If they want to know more they are given further information on rarer uses. Rebecca Roberts (RR) explained that Cells4Life staff will find out what the motivation is for banking, and if these are realistic, they are honest with parents about the potential uses. They have an extensive database of the diseases that are currently being researched and give parents information on clinical trials and approved treatment options for cord. Rachel Pawson (RP) also added that the NHS bank tells mothers what cord has been used to treat so far. Stephen Baines (SB) said that Future Health Biobank had a similar approach to Cells4Life in ascertaining the motivation for banking.

2. Paul Goggins (PG), MP for Sale and Wythenshawe East said that many of his constituents are frustrated because they are unable to donate their cord, especially following high profile patient appeals like Martin Solomon's. He is working with the Department of Health and Anthony Nolan to consider plans to establish a collection centre in Manchester.

Katie Begg (KB) said that awareness of donation is not as prevalent in the UK because we don't currently have a large public banking system like Spain or the USA. It would be frustrating to raise awareness amongst mothers generally when the majority will be unable to donate. Another cord centre in Manchester would help to meet the aims for stem cell transplantation in the UK, but this cannot be achieved without the appropriate level of funding.

3. Bob Dalgleish (BD) asked what the relationship was like between hospital trusts and cord collectors and if there was any cost involved for these hospitals.

RP said that the teaching hospitals that NHSBT and Anthony Nolan are based in are very supportive of collection as it also serves a research function. The fact that all the resources are provided by the collecting organisations makes it easier for hospital staff to support the project. Many centres also have haematology departments so they are aware of the importance and potential of cord blood. LM added that many staff working on the maternity units are happy to be involved in something so positive. RR noted that there are no costs to hospitals. There are some admin fees involved but these are met by private banks and are determined on a case by case basis depending on how much the trusts want to charge. Either way there is no net loss to the hospitals.

4. Rosemary Exton (RE) said that the RCM have had reports of private collectors entering the birthing room and failing to provide adequate information about active and physiological management of labour, as well as the implications for delayed cord clamping. She asked what the collectors are told on this topic.

SB said that third party phlebotomists contracted by Future Health Biobank are not authorised to enter the room. RR confirmed that Cells4Life phlebotomists do not enter the birthing room unless invited and also said that active and physiological management is discussed during the consent process and it is emphasised that this is a decision for the mother and her midwife to make. Cells4Life asks mothers to include a letter in their maternity notes that advise the midwife this service is requested and that once the cord is clamped and cut in accordance with the agreed birth plan, procurement should be undertaken as soon as possible.

5. Julie Frohlich (JFr) asked what proportion of donated units end up being released to the family. She also asked if units are made available to scientists working on publicly funded research.

RP said that mothers are asked if they would like to donate any units that are found to be clinically unviable to research. With regards to releasing publicly banked units to the family, in consultation with the family's clinician it would be advised that any donor child who develops a haematological condition in later life would not be best served by a transplant using their own cells. LM highlighted that Anthony Nolan consents for research during the general process, and all information provided is detailed and clear; mothers are informed that their cords may be used by commercial companies or in animal testing and that they are free to refuse consent to research for whatever reason.

6. Janet Fyle (JF) asked if private banks provide mothers with information on public banking. She also argued that by asking midwives to clamp the cord in a certain way, private banks are interfering in the birth process.

Both public banks said that they inform mothers of alternative banking options. RR stated that it was not the case that private banks are interfering in the birth process. Parents are given the option of suggesting directions for cord clamping in their birth plan, and are free to do so or not if they wish.

7. Julie Frohlich asked if private banks gave parents any information on how many cords they had released from their bank to customers, and whether the 1 in 5 statistic, referring the possibility of familial use, was conjecture and whether it was appropriate.

RR referenced this in her presentation. The [Harris study](#) – the reference for which can be found in the Cells4Life presentation - from 2007 found that if all current clinical trials resulted in standard treatments there would be a 1 in 5 chance of usage. Cells4Life has been operating since 2002; it has approximately 60,000 cord units stored and 3 have been released to date. Future Health Biobank has been operating since 2002; it has 70,000 units stored and has released 1 unit to date.

8. Dr. Paul Veys noted that as a transplant clinician he uses sibling cord from time to time. He asked how many Spanish private cords had been released publicly and if there was appetite for implementing a system similar to Spain's in the UK.

KB said that the secretariat team had been unable to find this information but would look into this further. SB noted that a significant number of Spanish parents bank abroad to avoid this system but a similar model could be introduced here. RR said that of the families choosing to store there were figures to indicate that 45% of Spanish families bank privately and 40% publicly compared to 0.1% doing either in the UK. But there is appetite for a dual model.

9. Laura Machin (LM) asked why the international examples given had focused on the USA, Spain and Cyprus.

KB and Victoria Moffett (VM) said that Spain was chosen because of the prevalence of cord donation, Cyprus because of the regulatory system, at the request of APPG Co-Chair, David Burrowes, and the USA because of the scale of donation and banking.

10. An observer asked what criteria is used to differentiate a cord suitable for clinical use from one that is not.

LM said that she did not know the exact figures but size of unit and number of stem cells will determine whether or not a cord is banked for clinical or research use. RP also highlighted

screening failures that arise post-donation can also have an impact on suitability for clinical use. RR said that as they provide a service they bank every unit but also provide information to parents on the public banking benchmark. SB confirmed that Future Health Biobank does the same.

11. Monica Del Olmo (MDO) asked what kind of information private banks give mothers about public banking and if there is a way to monitor this. She gave a recent example of a mother at the Royal Free hospital who banked privately because she was unaware that there were public banking facilities available.

SB confirmed that Future Health inform mothers of other options where appropriate e.g. in hospitals where public collection takes place. RR confirmed that Cells4Life tell all mothers about public banking as part of the sign-up process, irrespective of the hospital.

12. An observer asked who gives consent in situations where the mother passes away.

LM stated that the Anthony Nolan process follows enduring consent so it lasts forever; although this can be withdrawn at any time. She said that she is not aware of any situations where families had wanted to withdraw consent following the death of the mother. SB said that there is a legally-binding agreement with parents – usually the mother - until the child reaches 18. It was highlighted that public banks could face problems in the future as they would be holding tissue that belongs to adults without first obtaining their consent. LM accepted that this could be a problem in the future; such a situation might need to be tested in court.

13. Patrick Ojeer (PO) asked if a child is contacted at 18 to let them know that their tissue has been banked.

RP said that we haven't reached a time when this could become an issue yet but such information is probably best coming from the parents.

14. PO asked about the use of cord in research for other conditions such as sickle cell.

RP said that the NHS cord blood bank is aware that there is a need to provide for these requests; they are considering setting up as a biobank to streamline the process. RR said that they have received no requests from parents to release the cord for research, but to do so would be the choice of the parents.

15. An observer asked if there is a difference in clinical viability between publicly and privately banked units, and if this could be explained by the different operating models between the two. Public collectors get used to a process and are based in one hospital which offers routine and stability. Third party phlebotomists to private centres might struggle to achieve this.

RP stated that the public threshold was now 140×10^7 and that with this higher threshold, two thirds are available for research. RR stated that 90% of the cords banked by Cells4Life globally meet or exceed the threshold.

16. PO asked what research projects are currently using cords from public banking programmes.

Salmah Mahmood pointed out that Anthony Nolan is a biobank and releases cords for a number of projects. Cords are not discarded and information on what research cords have been released for so far can be made available. Terie Duffy said that current projects at King's were studying asthma and how a stem cell becomes leukaemic.

17. Orin Lewis (OL) asked what is being done to raise awareness about donation amongst BME communities in order to meet the BME patient need.

RR said that there has generally been greater interest and awareness from parents from BME backgrounds but Cells4Life do not market their services and certainly not by ethnicity so they cannot take credit for this. LM said that Anthony Nolan establishes collection centres in areas of high ethnic diversity. The cord collection centres broadly follow the organisation's national campaigns and marketing materials are also reflective of the local population. RP said that the NHS cord blood bank follows a similar approach dependent on the aims of the NHS Blood and Transplant BME strategy. They have also been employing multi-lingual collectors and have seen a real difference in take-up after 1 month.

18. An observer asked about the protocol behind directed cord donations if the unit is found not to be a suitable match.

RP confirmed that where a directed donation cord is not viable for clinical use due to family history of blood cancer, parents are given the option of private storage, as this cord will not be appropriate for public banking.

19. An observer asked whether there was a planned policy change to a US system, whereby a parent could receive a transplant from a cord banked from their child's birth.

RP suggested that this would depend on the indication, as to whether a transplant was a viable option at all.

20. JF noted that there has been some discussion about the current default position for cord and placenta use after birth being discarding, which is not ideal. She asked what critics suggest midwives should do at this stage of the birth process.

RR said that mothers should be given an active role in the decision on what to do with their placenta and/or cord. RE noted that this isn't practical, neither is it the responsibility of the midwife to signpost any options available; this might be possible in hospitals with public banking facilities but it cannot be done on a larger scale. RR said that the current situation is not ideal and that there needs to be more thinking and collaboration on this issue from all those with an interest in improving the uptake of cord blood banking.