







Our Mission

To cost effectively provide high quality cord blood units for life-saving transplants for patients with leukaemia and certain other blood and genetic diseases and to develop through research new therapeutic applications for cord blood products.

The Queensland Cord Blood Bank at the Mater continues the ministry of the Sisters of Mercy to provide the highest quality health care to the sick and needy without discrimination.



Contents

Introduction	4
How do I become a cord blood donor?	5
What does being a donor involve?	5
Do I have any responsibilities as a cord blood donor?	8
Is there anyone who should not be a cord blood donor?	9
Is there any risk to me or my baby if I donate my cord blood?	12
Research projects at Mater	13
Confidentiality of information	14
Summary	14
Frequently asked questions	16
Appreciation	19
Appendix	20

The Queensland Cord Blood Bank at the Mater operates two cord blood collection centres:

Mater Mothers' Hospital

Raymond Terrace South Brisbane QLD 4101 Phone: 07 3163 1614

Logan Hospital

Armstrong Road Meadowbrook QLD 4131 Phone: 07 3299 8502



Introduction

During pregnancy blood from the umbilical cord provides the life-link between you and your baby. It could also provide a lifeline to a child suffering from leukaemia. You can share the joy of your baby's birth with the gift of life to a patient in need of a transplant by donating your baby's cord blood to the Queensland Cord Blood Bank at the Mater.

Traditionally the placenta and umbilical cord have been discarded after childbirth. Now, in the ultimate form of medical recycling, blood can be collected from the placenta via the umbilical cord (cord blood) and frozen and stored to create a bank of blood-forming stem cells, which are similar to those found in bone marrow. These stem cells can be used in life-saving transplants for patients with leukaemia, certain other blood disorders and genetic diseases. In the future, patients with other diseases may also benefit from stem cell therapy.

If you consent to be a cord blood donor, the collection will not interfere with normal delivery procedures. After delivery of your baby and placenta, the placenta will be taken away for collection of the cord blood. Before discharge from hospital, you will be required to provide a medical history and blood samples. You will also be required to return 6-7 months later for repeat testing on your blood and to answer a brief questionnaire.

This booklet provides information to assist you in your decision to be a cord blood donor.



How do I become a cord blood donor?

- ~ Read this booklet
- Phone or speak to a staff member of the Cord Blood Bank if you have any further questions or concerns
- ~ Complete a consent form
- Return the form to the hospital
 on your next visit, by post or
 when you present to the delivery suite.



What does being a donor involve?

We would seek your written consent for the following:

After the delivery of your baby and the placenta

~ to collect blood from the placenta via the umbilical cord

Prior to discharge from hospital

- to complete the cord blood donor declaration form (similar to that completed by regular blood donors)
- to provide information about your pregnancy and a full medical and family history
- to review you and your baby's hospital medical records and to contact your doctor or health professional if necessary to obtain additional medical information should this be necessary to confirm that your baby's cord blood is suitable for transplant

- to collect blood from you (where possible, the blood would be collected at the same time as other blood tests you may need)
- to tissue type your blood and your baby's cord blood in order to match the cord blood with samples from patients needing a transplant
- to perform tests on your blood and your baby's cord blood for bacterial and viral infections, sexually transmitted diseases and other diseases that are transmissible by blood products (refer to Appendix)
- to perform other tests on your baby's cord blood as considered appropriate to determine its safety and quality for transplant
- to store samples of your blood and your baby's cord blood for the purpose of future testing if required as scientific knowledge advances
- to freeze and store your baby's cord blood and to use it for transplant of patients anywhere in the world

6-7 months after delivery, if your baby's cord blood has been banked

you will be asked to return to the hospital and give a second blood sample (of your blood not your baby's blood) to be tested again for infectious diseases and to complete a short questionnaire about you and your baby's health since the delivery







Do I have any responsibilities as a cord blood donor?

Cord blood donors have the same responsibilities as other blood donors.

It is required by law that you complete a donor declaration form stating that you do not have a high risk of transmitting infection.

It is against the law to make a false or misleading statement in a declaration or questionnaire relating to the donation of blood. Any person who does so is liable to severe penalties or imprisonment. If in doubt, please discuss your concerns with your medical officer or a staff member of the Cord Blood Bank.

Is there anyone who should not be a donor?

You should not be a cord blood donor if:

- you are aged less than 18 years or more than 45 years old
- ~ you are less than 36 weeks gestation at the time of delivery
- you do not know or are uncertain of the identity of your baby's father
- ~ you are related to the father of your child.

Within the last 12 months you:

- have had a tattoo (including cosmetic), skin piercing, acupuncture or electrolysis where single use disposable equipment was not used
- have been injured with a used needle/syringe
- have had a blood transfusion or blood products
- had a blood/body fluid splash to eyes, mouth, nose or broken skin
- had (yellow) jaundice or hepatitis or been in contact with someone who has, or
- been imprisoned in a prison or lock-up for more than 72 hours.

Within the last 6 months you:

 have had persistent fever, night sweats, diarrhoea or swollen glands or unexplained weight loss

You should also not be a cord blood donor if you or your partner*:

- ~ are infected with or have been infected with the HIV (AIDS) virus
- ~ have ever injected or been injected with a drug not prescribed by your doctor

Have had sexual contact with a person whom you know:

- ~ has been exposed to the AIDS virus, or
- ~ has shared needles or syringes, or
- has had sex with a male who had sexual contact with another male in the last 5 years, or
- ~ has had sex with a male or female sex worker (prostitute) here or overseas
- ~ have engaged in sexual activity with a new partner during your pregnancy.
 - * "Partner" is defined as any person with whom you have had sexual contact in the last 12 months.







Is there any risk to me or my baby if I donate my cord blood?

- There is no risk to you or your baby from the collection of cord blood.
- Our staff are fully trained and will take every care in taking blood samples from you for testing.
 However there is a small risk to you of bruising. Thus, it is important to follow staff instructions after having blood samples collected.
- There could be undue concerns, anxiety or stress associated with a positive test result obtained for one of the infectious diseases.

To help you understand these potential risks more clearly a detailed explanation on the tests performed for HIV and other infections can be found in the Appendix of this booklet.

Research projects at the Mater

If for some reason you cannot or do not want to be a cord blood donor you can donate your cord blood for research studies.

We are committed to quality in all aspects of our programme.



We hope through research projects at the Mater:

- to improve the methods used for cord blood banking by validation and quality control of all procedures
- to develop methods to "expand" or multiply the number of cells in individual cord blood units so that this therapy can be used for adults
- to develop new tests and normal ranges to assist in the diagnosis of disease in newborn babies, and
- to explore the role of dendritic cells, which are vital to the immune system.

This research will allow us to examine methods to improve the safety of cord blood for transplantation. It will also provide valuable information in relation to the effect pregnancy complications have on the blood system of newborn babies.

Confidentiality of information

All information, whether in record or database format, including you and your baby's identity and all test results will be kept in strict confidence and stored securely. However, we are required by law to notify the relevant authorities if a positive test result is obtained for HIV (AIDS), HTLV I and II, Hepatitis B and C and Syphilis. Information released to Registries and Transplant Centres or used for publications will be coded in anonymous format. Records and databases will be kept however that link donors to the cord blood donation, allowing for any required follow-up.



Summary

As a donor, it is important that you have read and understood this booklet, are aware of your responsibilities as a donor and had any questions answered to your satisfaction.

The Mater Health Services Human Research Ethics Committee has approved the processes involved in the collection and banking of cord blood and selection and release of cord blood products for transplant according to regulatory guidelines and all associated research projects.



Frequently asked questions

What is so special about cord blood?

Cord blood has unique features:

- ~ it is rich in stem cells similar to those found in bone marrow
- it can be used instead of bone marrow for transplant of patients with leukaemia, certain blood disorders and some genetic diseases. In future, patients with other diseases may also benefit from stem cell therapy
- ~ it has a very low risk of being contaminated by viruses
- ~ the donor is a newborn baby with an immature immune system.

What are the advantages of cord blood compared to bone marrow for transplant?

- ~ it is easier and quicker for patients to find a suitable donor
- ~ there are fewer life-threatening complications
- ~ there is a lower risk of viral infection following transplantation.

Does cord blood have any disadvantages compared to bone marrow for transplant?

The main disadvantage of cord blood for transplant is that there are fewer cells in cord blood than in bone marrow. Thus at this stage cord blood is suitable mainly for children and small adults.





Why are cord blood banks being established around the world?

A global network of cord blood banks could provide a readily available source of donors for patients who require a bone marrow transplant but do not have a suitable donor.

Unfortunately, more than half of the patients with lifethreatening diseases such as leukaemia who are eligible for a bone marrow transplant do not have a suitable donor. It is particularly difficult to find donors for patients from ethnic minority groups who are not well represented in the large volunteer donor programs.

If I agree to be a donor, will my cord blood definitely be collected and banked?

Consent to donate cord blood will not guarantee that it will be collected or banked.

Your baby's cord blood may not be collected if your delivery occurs outside the normal operating hours of the bank, if there are any medical problems with the delivery or if the cord blood is required for other testing.

A certain number of cells are required to perform a successful cord blood transplant. If the cord blood collected does not have enough cells, or is unsuitable for other reasons, it will not be banked. In these cases, if you have given your permission, the cord blood may be used for important laboratory research. If you have not given permission for research, it will be discarded.

Is there any way to increase the number of cells in cord blood so that it is more suitable for transplant to adults?

It is possible to increase the number of cells by culturing the stem cells in the laboratory with a cocktail of growth factors, which stimulate cell multiplication. This technique is known as ex vivo expansion.

The Lions Medical Research Foundation has funded a research study to develop this technique. If your cord blood is unsuitable for banking you may consent for it to be used for this important research project.

Will I be notified if my baby's cord blood is used for a transplant?

No. This is to protect the privacy and confidentiality rights of the transplant patients and their families.

Are embryonic stem cells collected?

Stem cells that can reproduce the entire blood system are an essential component of a cord blood transplant to treat certain diseases. Embryonic stem cells are an earlier form of stem cells, which can produce not only blood cells but also a range of tissues such as brain, liver, muscle and cartilage. There may be stem cells in cord blood that are similar to those found in the early embryo (the fetus before implantation in the uterus). However, no aspect of cord blood donation or transplantation involves the manipulation or destruction of early embryos.

If I have any questions or concerns?

If you require further information or would like to discuss any issues with our staff, please telephone one of our Collection Centres:

Mater Mothers' Hospital Collection Centre (07) 3163 1614

Logan Hospital Collection Centre (07) 3299 8502

You may wish to discuss the above information with your family or your doctor before making your decision.



Appreciation

We thank you for considering donation of your baby's cord blood to the Queensland Cord Blood Bank at the Mater. Ultimately, this blood may be used for transplantation into patients — at this stage mostly children with leukaemia and certain other lifethreatening disorders. You will be making a generous gift to the community.

Your contribution is greatly appreciated.

Queensland Cord Blood Bank at the Mater

Telephone: 07 3163 1614

Director: Dr Robyn Rodwell

Medical Director: Dr Clare Morgan

Appendix

Information on the tests performed for HIV (AIDS virus) and other Infections.

Certain infections including HIV (AIDS virus) can be transmitted through blood products. To ensure that your baby's cord blood is safe for the person who receives it, your blood and your baby's cord blood will be tested for HIV I and II (AIDS virus), Hepatitis B and C, HTLV I and II, Syphilis, CMV and certain other infections. You will also be asked to provide a medical history and to sign a declaration form that you are not at risk for the transmission of these infections.

These infections may be transmitted by blood transfusion, sexual contact with an infected male or female, needles shared with an infected person, or by exchange of body fluids by any means.

When a person is infected with HIV, the immune system produces antibodies. These can be measured by an antibody test. It usually takes 2-8 weeks for these antibodies to appear, but it may take longer. This period of time is called the 'window period'. During the window period antibody testing may not detect the presence of infection. Thus blood tests performed at birth may not detect an infection acquired in the 3 months prior to delivery. For this reason you are asked to return for a repeat test on your blood 6-7 months after delivery.

A negative result for the HIV antibody test for the AIDS virus means that antibodies are not present in the blood:

- ~ because the blood is not infected with HIV, or
- because it is very early infection (window period) and antibodies have not yet been produced.

A positive result for the HIV antibody test means either:

- ~ that a true HIV infection is present, or
- that the result is a false positive and that there is no infection.

A repeat antibody test and other tests are then performed to distinguish a true infection from a false positive test.

A false positive test result may occur for a number of reasons. Most commonly it is due to pregnancy-related changes in the protein content of the blood. Repeat testing including molecular (DNA or RNA based) testing can usually distinguish between a false positive test result and a true infection. However, this process may take several weeks to months.

A positive antibody test even if we believe it to be a false positive result cannot be ignored, as we must do the extra tests to be certain that true infection is not present. A true infection would have implications for you and your baby's health. It would also raise the question of how and when you might have contracted the infection.

If tests confirm a true infection your Doctor and you will be notified. You will be given the opportunity for counselling and further assessment and treatment.

The relevant health authority will also be notified as required by law.

Cytomegalovirus (CMV)

One of the other tests performed on the cord blood to ensure that it is safe for the patient who receives it is a test for the virus CMV. Under normal circumstances, this test is not routinely performed on cord blood. Very rarely we may obtain a positive test for CMV. This indicates that the baby may have been infected with CMV during pregnancy even though the baby is asymptomatic at birth.

If a baby has been infected with CMV during the pregnancy and is asymptomatic he/she has a less than 1 in 10 chance of problems developing. These include hearing loss and eye problems. If your baby is infected with CMV, you and your Paediatrician (or a hospital Paediatrician) will be notified and assessment and appropriate tests recommended. This may benefit your baby as your Paediatrician could organise audiology screening to detect hearing loss, and if it occurs, early detection and intervention may improve your child's language development.

On the other hand, in most cases (9 out of 10) a positive test on cord blood for CMV will not be associated with any subsequent clinical problems. In this situation knowing this result could theoretically (although we are not aware that this has ever happened) affect you or your baby in matters such as health insurance if you do not have family cover, or other insurances, such as life insurance.

The Queensland Cord Blood Bank at the Mater is a Ronald McDonald House Charities Cord Blood Bank.



It is also a member of AUSCORD the National Cord Blood Collection Network funded by the Federal/State and Territories Governments to collect cord blood for use in patients in need of transplant.



The Queensland Cord Blood Bank at the Mater was developed through the generosity of the Lions Clubs of Queensland and northern New South Wales, the Leukaemia Foundation, Ronald McDonald House Charities, City Automotive Group and many other community groups and individuals throughout Queensland and northern New South Wales.

The Lions Cord Blood and Leukaemia Research Unit was established by the Lions Medical Research Foundation to support research in this area and provides ongoing recognition of the major contribution of the Lions Clubs of Queensland and northern New South Wales to the development of the Queensland Cord Blood Bank at the Mater.







Issue Date: 17-05-2004