

Information for couples where both partners carry Haemoglobin Lepore Thalassaemia

Including Information about Prenatal Diagnosis

Contacts for prenatal diagnosis centre

Couple at risk for a Serious Form of Thalassaemia

	Name	Date of Birth
Ms		
Mr		

- *You both carry haemoglobin Lepore thalassaemia. This means that, as a couple, you are at risk for having children with thalassaemia intermedia or major. This booklet explains about this risk, and how you can avoid it.*
- *Your full blood test results are given below.*
- *Keep this booklet with your personal papers, so that you can refer to it again. Show it to your doctor and midwife in every pregnancy.*

Blood test results

Name	Date of Test	Hb	MCH	MCV	Hb A ₂	Electro-phoresis	DNA data*

** this is essential information for all couples at risk for alpha or beta thalassaemia*

Centre where tests were done

Address	
Telephone	Fax
Other	

Issued

Date
Signature of Doctor or Counsellor

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Part 1.

What is an “At Risk Couple”?

You both carry haemoglobin Lepore thalassaemia. You are both healthy but you could have children with a serious haemoglobin disorder. This is why you are called an “at risk couple”. Your blood test results are written in the front of this booklet.

Haemoglobin Lepore thalassaemia is a form of beta thalassaemia. These are among a range of variations in the blood, that doctors call “*haemoglobin disorders*”.

What are haemoglobin disorders?

Haemoglobin disorders cause changes in the haemoglobin in a person's red blood cells. They are *inherited* - they are handed on from parents to their children, they are present at birth, and they remain the same for life.

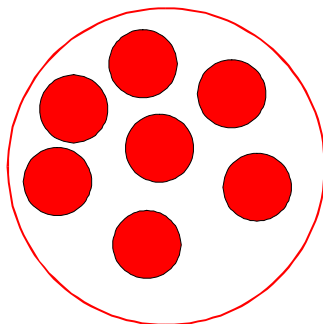
Haemoglobin is a component of the blood. It contains iron, which makes it bright red. This is why your blood is red. Your body needs oxygen to function: as your blood circulates haemoglobin picks up oxygen in your lungs and carries it round to all parts of your body. The usual type of haemoglobin is called haemoglobin A.

Haemoglobin is packed into *red blood cells*. Blood contains millions of red blood cells floating in a slightly yellow fluid called plasma.

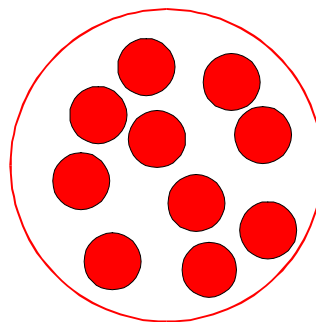
What is haemoglobin Lepore thalassaemia?

People who carry haemoglobin Lepore thalassaemia have smaller red blood cells than other people. They make up for having small red blood cells by making more of them. They also have a small amount of an unusual haemoglobin called *haemoglobin Lepore* in their blood. Their blood functions normally, and they are healthy people.

The picture shows the usual kind of red blood cells, and a haemoglobin Lepore thalassaemia carrier's red blood cells, seen down a microscope.



Usual red blood cells



A haemoglobin Lepore thalassaemia carrier's red blood cells

How do you find out you carry haemoglobin Lepore thalassaemia?

People find out they carry haemoglobin Lepore thalassaemia through a special blood test called a *haemoglobinopathy screen*. This shows that:

- they have small red blood cells.
- they have between 7 and 15% of haemoglobin Lepore in their blood.

People who carry haemoglobin Lepore thalassaemia are usually said to carry "haemoglobin Lepore", for short. From here onwards we use the term haemoglobin Lepore.

How is haemoglobin Lepore inherited?

It is inherited through *genes*. Every human characteristic, such as eye colour, or height, or type of haemoglobin is controlled by genes that we inherit from our parents. A child inherits *two* genes for every characteristic, one from each parent. Most people have inherited two genes for *haemoglobin A*. This is the usual type of haemoglobin.

A haemoglobin Lepore carrier has inherited a gene for haemoglobin A from one parent and a gene for haemoglobin Lepore from the other. Their haemoglobin Lepore gene can make only a small amount of haemoglobin. Their normal haemoglobin A gene makes enough haemoglobin for their red blood cells to function normally.

When both of a couple carry haemoglobin Lepore a child could inherit a haemoglobin Lepore gene from both parents. Neither of their haemoglobin genes can function normally, and their red blood cells contain much less haemoglobin than usual. This causes a serious anaemia.

- If the anaemia is severe and the child needs regular blood transfusions, this is *thalassaemia major*.
- If the child can manage without regular blood transfusions the anaemia is called *thalassaemia intermedia*.

We cannot predict how severe the anaemia would be in any particular case. However, a child with two haemoglobin Lepore genes is more likely to have thalassaemia intermedia than thalassaemia major.

What are your chances of having children with a serious form of thalassaemia?

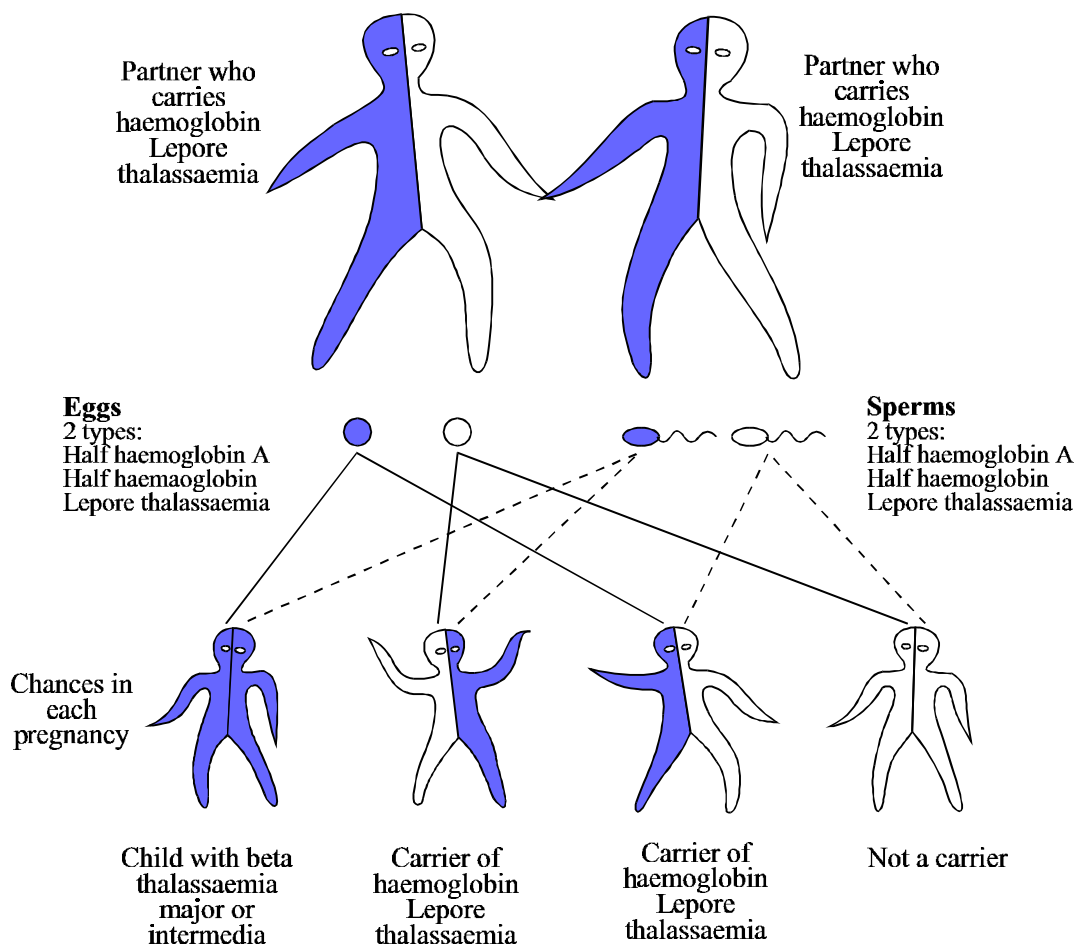
Couples who both carry haemoglobin Lepore have the following chances *in each pregnancy*

- a 1-in-4 chance of a child that is not a carrier
- a 1-in-2 chance of a child that is a healthy carrier of haemoglobin Lepore
- a 1 in 4 risk of a child with with a serious form of thalassaemia.

In every pregnancy your chance of having a healthy child is much higher than your risk of having a child with a serious form of thalassaemia.

How could a child inherit a Serious Form of Thalassaemia from you?

When a child is conceived, it inherits one gene for haemoglobin from each parent. The picture shows that when both parents carry haemoglobin Lepore there are four possibilities.



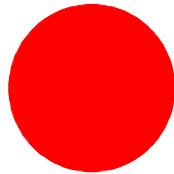
Women usually produce one egg each month. When a woman carries haemoglobin Lepore, each egg contains either her normal haemoglobin gene or her haemoglobin Lepore gene, but not both.

Men make sperm all the time. When a man carries haemoglobin Lepore, each sperm carries either his normal gene or his haemoglobin Lepore gene, but not both.

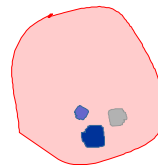
- If a normal egg is fertilised by a normal sperm, the child will not carry any haemoglobin disorder.
- If a normal egg is fertilised by a haemoglobin Lepore sperm the child will carry haemoglobin Lepore .
- If a haemoglobin Lepore egg is fertilised by a normal sperm the child will carry haemoglobin Lepore .
- If a haemoglobin Lepore egg is fertilised by a haemoglobin Lepore sperm, the child will have thalassaemia intermedia or thalassaemia major.

What causes Thalassaemia Major or Intermedia?

Normally, red blood cells are produced in the bone marrow, live for about four months, and then are broken down and replaced by new red blood cells. People with one beta thalassaemia gene and one haemoglobin Lepore gene cannot make haemoglobin A normally, and their bone marrow cannot make red blood cells normally. They make some haemoglobin Lepore, and also some haemoglobin F, but their red blood cells contain too little haemoglobin, and they often have a severe anaemia.



A normal red blood cell



A beta thalassaemia major or intermedia red blood cell

Can you predict whether a couple could have children with thalassaemia intermedia or thalassaemia major?

In most known cases, a person who has inherited two haemoglobin Lepore genes has thalassaemia intermedia. However, it is not possible to be absolutely sure that they would not have thalassaemia major.

What is Thalassaemia Intermedia?

A child with thalassaemia intermedia is normal at birth, but becomes slightly anaemic by one year of age. The anaemia becomes gradually more marked up to two to four years of age. Then it usually settles at a steady state.

Children with thalassaemia intermedia do not need regular blood transfusions. However, it is an unpredictable condition.

- A few people with thalassaemia intermedia have only a mild anaemia, and lead a normal life.
- Many children with thalassaemia intermedia have a moderate anaemia and are not as strong as others. They may need a blood transfusion from time to time, for example if they have an infection. The anaemia may get worse with age, and they may have to put up with chronic health problems.
- Some people with thalassaemia intermedia may need to start on regular blood transfusions when they are adolescents or young adults. Then their treatment is the same as the treatment for thalassaemia major.

With appropriate medical care, children with thalassaemia intermedia grow up normally, and have a normal education. Most adults with thalassaemia intermedia work normally, find a partner, and many have a family.

What is Thalassaemia Major?

A child with thalassaemia major is normal at birth but becomes anaemic at between three and eighteen months of age. The child becomes pale, does not sleep well, does not want to eat, and may vomit feeds. A child who is not treated has a miserable life, and is likely to die by eight years of age.

What is the treatment for thalassaemia major?

The treatment for thalassaemia major is regular blood transfusions, usually every four weeks. Children who have regular transfusions grow and live normally. But to live past their twenties, they need other treatment as well.

After each blood transfusion the transfused red blood cells break down slowly, and the iron they contain stays in the body. If it builds up it can damage the liver, the heart and other parts of the body. Fortunately, extra iron can be removed from the body by a drug called desferrioxamine (or Desferal®). This picks up iron and brings it out in the urine. It is injected under the skin using a small portable "pump", over 8-12 hours on 5-7 nights of each week.

With this combined treatment people with thalassaemia major can lead a nearly normal life. Children with thalassaemia major grow up normally, and have a normal education. Adults with thalassaemia major work normally, find a partner, and many have a family. However, the life-long treatment is very burdensome and sometimes upsetting. Researchers are looking for better treatments all the time.

How long do children with thalassaemia major live?

A child born today with thalassaemia major should live an almost normal length of life, providing they take all their treatments regularly.

Is there a cure for thalassaemia major?

Some thalassaemic children can be "cured" by bone marrow transplantation. This is not an easy solution. The child must be given bone marrow taken from a brother or sister (or occasionally a parent) who *exactly* matches their own tissue type. Each brother or sister has a 1-in-4 chance of being an exact match. Bone marrow transplantation also involves serious risks to the patient's life and health.

Do thalassaemia major or intermedia have any effect on an unborn baby?

No, an unborn baby with thalassaemia major or intermedia develops normally. This is because unborn babies have a special type of haemoglobin called *fetal haemoglobin* or *haemoglobin F*.

Haemoglobin F is different from haemoglobin A. It is produced by different genes. The haemoglobin F genes usually work until a baby is born. After birth a baby's haemoglobin F genes are usually switched off and its genes for haemoglobin A are switched on. This change is called the "fetal switch". It takes about six months.

When an unborn baby has thalassaemia major its haemoglobin F genes work normally, so the baby is normal at birth. The child begins to get anaemic after six months of age because its genes for haemoglobin F have been switched off, but its genes for haemoglobin A do not work properly.

What are the hopes for people with a serious form of thalassaemia in the future?

Research is presently going on the following new developments.

- **Increasing the amount of fetal haemoglobin in the blood.** People with a serious form of thalassaemia cannot make haemoglobin A normally. Their red blood cells contain some haemoglobin because they keep a little haemoglobin F after the "fetal switch" has happened. The haemoglobin F is good for them, but they have not got enough of it. If the haemoglobin F genes could be switched back on, their anaemia would improve. A drug called *hydroxyurea* seems to switch some haemoglobin F back on, in a few people with a serious form of thalassaemia.
- **An oral iron chelating agent.** A drug for removing iron, that can be taken by mouth, is being tested world-wide. It is called Deferiprone. It is not as safe as desferrioxamine and it is inconvenient to take, but many thalassaemics may be able to use it sometimes instead of the "pump" in the near future.

- ***“Intra-uterine bone marrow transplantation”***. It might become possible to treat a fetus with thalassaemia major during early pregnancy. This might make the disease milder, so that the child would be more like a carrier than a person with thalassaemia major.
- ***“Gene therapy”*** may become possible for thalassaemia in the next 10 to 20 years. However, it will probably be more complicated and expensive than it sounds.

Finding out if your Baby is Healthy or has a Serious Form of Thalassaemia

Most couples wish to know the answer to this question as early as possible.

Finding out during pregnancy

You can find out during pregnancy, through *prenatal diagnosis*. This test can be done at any time after 11 weeks of pregnancy. If the baby does not have a serious form of thalassaemia this is reassuring. If the baby has a serious form of thalassaemia you can choose to terminate the pregnancy and try again, or to continue the pregnancy and plan the best care for the baby.

- Most couples at risk for thalassaemia ask for prenatal diagnosis in every pregnancy, and many have built up a family of 3 or 4 healthy children in this way.
- Some couples decide not to have prenatal diagnosis because there is a small risk to the pregnancy, or for other reasons.
- Some couples ask for prenatal diagnosis even though they have not decided what to do if the baby has a serious form of thalassaemia.
- Some couples ask for prenatal diagnosis even though they will not terminate the pregnancy if the baby has a serious form of thalassaemia.

These decisions are all perfectly acceptable.

Finding out when the baby is born

You can also find out soon after the baby is born, through *neonatal diagnosis* (new-born diagnosis).

All at-risk couples who continue a pregnancy ask for neonatal diagnosis, whether they have had a prenatal diagnosis or not.

Couples who have had a prenatal diagnosis want the result confirmed when the baby is born. Couples who have not had a prenatal diagnosis want to know whether the baby is healthy or not as soon as he or she is born.

Neonatal diagnosis for thalassaemia is done on blood taken from the baby's cord at birth, or from a heel-prick done a few days later. The only reliable method is DNA analysis.

For parents who have had a prenatal diagnosis, the prenatal diagnosis laboratory provides a blood bottle, a request form and a padded envelope, so that parents can ensure a blood sample is taken and can send it to the laboratory. The prenatal diagnosis laboratory informs parents (and their GP, counsellor and other specialist) as soon as they have the result.

Are you interested in Prenatal Diagnosis?

If you are interested in prenatal diagnosis, now or for the future, you should visit the prenatal diagnosis centre and talk with an expert counsellor. If you are unsure, a visit may help you to make up your mind. To make an appointment, phone the number on the front of this booklet directly, or ask your counsellor or family doctor to make an appointment for you.

This is your decision, about your family. No-one will put pressure on you to doing anything you do not really want to do.

Please come early!

The staff of the prenatal diagnosis centre like to meet “at risk” couples before they get pregnant, or as soon as possible after a pregnancy has started . You need time to decide whether you want prenatal diagnosis or not. Also, the staff needs a little warning so that they can plan their work.

If you are planning to have a baby, and think you may want prenatal diagnosis, ask your family doctor or sickle cell counsellor to make an appointment for you with the centre. You can also contact the centre directly to make an appointment.

If you are already pregnant and want to know more about prenatal diagnosis, contact the prenatal diagnosis centre immediately. They will give you an early appointment, and will answer your questions and help you make the right decisions for yourselves and your baby.

Part 2.

Prenatal Diagnosis

Couples interested in prenatal diagnosis need to visit the prenatal diagnosis centre for a consultation. A separate visit is needed for the test (if you decide to have it).

Visit 1 (allow about 1 ½ hours)

Both parents should attend, if possible. The counsellor will:

- *take blood from both parents for DNA tests*
- *discuss thalassaemia intermedia and major, present treatment, and hopes for the future*
- *discuss your risk and the advantages and disadvantages of the tests, and answer all your questions*
- *make up your medical notes*

If you are pregnant, the counsellor will:

- arrange an ultrasound scan to check the pregnancy
- explain which test would be best for you, based on the ultrasound scan
- help you make the best choice for yourselves
- make an appointment for the test, if you decide to have it

Visit 2: The test (allow a whole morning)

You come to the *fetal medicine unit* at the hospital, in the morning. Ideally both parents come together. The fetal medicine team do an ultrasound scan to see exactly where the baby and the placenta are. Then they do the test that is most suitable for you. You are not put to sleep. You go home a few hours later.

How is Prenatal Diagnosis done?

The test is done in one of two ways. In *chorionic villus sampling* a very small amount of tissue is taken from the placenta. In *fetal blood sampling* a very small amount of blood is taken from the baby. Tests can be done between 9 and 22 weeks of pregnancy (or even later) - but obviously the earlier the better. The right test for you depends on the stage of your pregnancy and the position of the placenta.

The the material is used to examine the baby's haemoglobin genes. This is called "*DNA analysis*". Many different changes in haemoglobin genes can cause thalassaemia. Therefore it is necessary to study both parents to find out the exact change in your DNA. If the laboratory cannot identify your exact type of thalassaemia, they may need to study blood from your parents, or brothers or sister, or children if you already have any. In order not to do the test in a rush, it is best to study the parents (and other family members if necessary), before or very early in pregnancy.

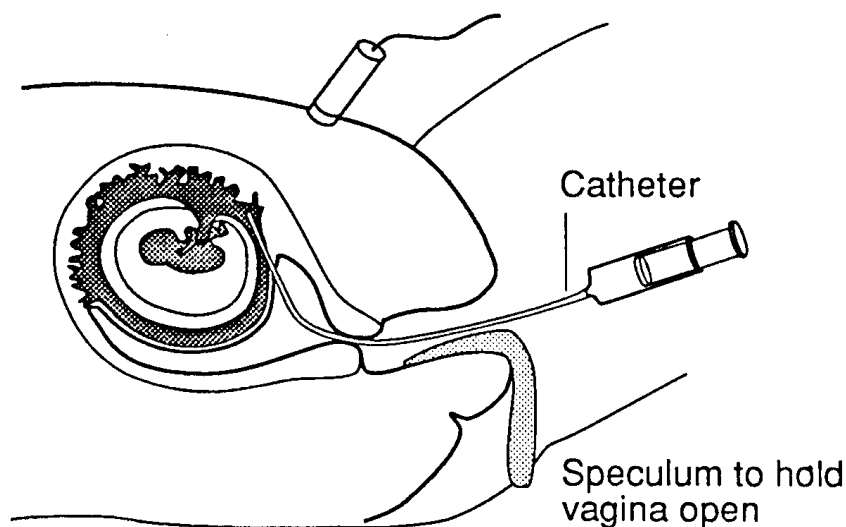
Chorionic Villus Sampling

This test is called *CVS* for short. CVS can be done at any stage of pregnancy, but the best time is between 10 and 12 weeks after your last menstrual period (8-10 weeks after the child was conceived.) An early test is best, because if you consider terminating the pregnancy, an early termination is much less upsetting than a later one.

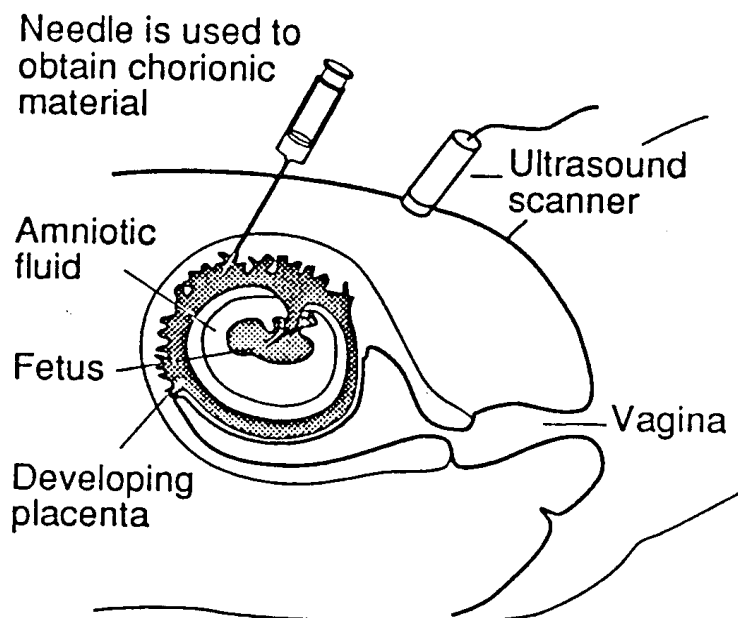
The obstetrician takes a small amount of material from the developing placenta. The placenta is where the baby is attached to the mother. It develops from the tissues of the baby, not the mother, so it has the same make-up as the baby. It is made up of "chorionic villi".

The obstetrician can obtain a sample of chorionic villi either through the vagina, or through the abdomen (tummy). The best method for you depends on the position of the placenta, and also on your preference. The team use an ultrasound scanner all the time, to see exactly what they are doing.

CVS through the vagina. The obstetrician puts a very thin plastic tube through the vagina and then into the womb. It is so thin that most women hardly feel it. It does not touch the baby or the little bag of water around it. Then the obstetrician attaches a syringe to the end of the tube and withdraws a very small amount of chorionic villi. This is called *trans-cervical CVS*. The picture shows how it is done.



Sometimes it is not possible to reach the placenta through the vagina. Then it can be reached by putting a long thin needle through the tummy. The obstetrician injects local anaesthetic to "freeze" the skin before inserting the needle. The local anaesthetic stings and there is a brief feeling of pressure when the needle is put in, but there should be very little pain. When the ultrasound picture shows that the needle is in the right place, the obstetrician fixes a syringe to it and withdraws some chorionic villi. This is called "trans-abdominal CVS". The picture shows how it is done.



Once some tissue has been obtained, a member of the team immediately looks at it under a microscope to check that it is from the placenta. If it is, the procedure is finished. If it is not, the obstetrician moves the tube or needle slightly and tries again. It can take 2 or 3 tries to get the tissue. The test usually takes 10 to 20 minutes.

After the test, you rest in the hospital for about half an hour, and then go home. Take things easy for one or two days: this means you can go about as usual, but should avoid heavy work. Avoid sexual intercourse for 10 days after the test. If the test has been done through the vagina, you may see some blood spots for a few days. This is usually harmless. However, if there is a lot of blood, or if you have pain or fever, contact the team immediately at the phone number they give you at the hospital.

How is the chorionic villus sample tested?

The genes for the characteristics we inherit, including haemoglobin, are made of DNA. Every tissue in the body contains the person's entire DNA pattern. In the fetus, this includes the placenta. The laboratory staff study the DNA from the chorionic villi, to see if the baby's haemoglobin genes will make the child normal or a carrier, or whether the baby will have a serious form of thalassaemia. This usually takes about a week. The counsellor tells you the result as soon as possible, usually by telephone.

Is the DNA test accurate?

DNA analysis is the best method for diagnosing inherited disorders. However, there is a small possibility of a mistake in every medical test. All human beings can make a mistake however careful they are. Rarely nature itself "plays a trick" that makes us make a mistake. So there *is* a chance of a mistake with this test, but it is very small, less than 1 in 400 (0.22%).

Also, if the male partner is not the real father of the baby, the result on the baby may not be correct. ***If the mother thinks there is any possibility that her partner is not the real father, she should tell the***

counsellor confidentially. Any such information be kept strictly confidential. It is only needed to avoid a mistake in the result.

Is CVS safe?

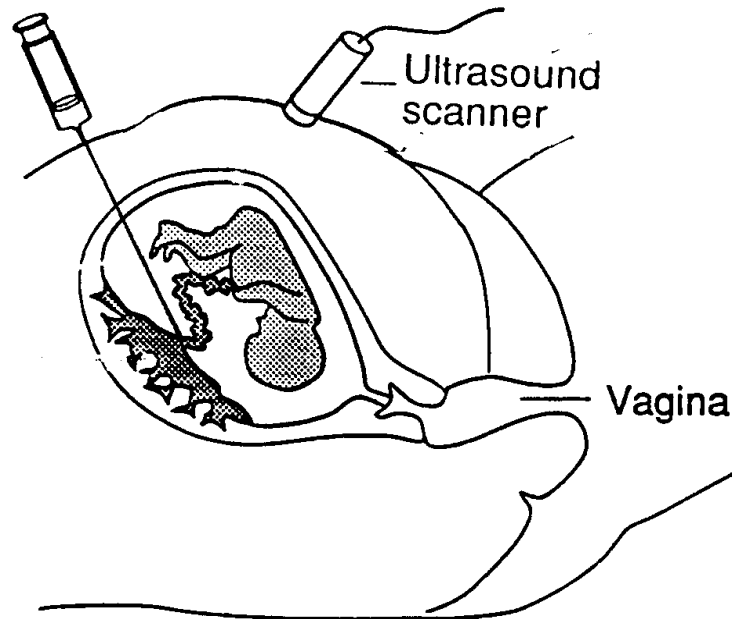
There is no risk to the mother. The main risk is that the test could cause a miscarriage. The doctors do the test as gently as possible, but anything that interferes with a pregnancy may cause a miscarriage. At the moment, when CVS is done before 12 weeks of pregnancy the risk of miscarriage seems to be around 1 in 50 (2%). When a miscarriage does occur, it can be difficult to tell whether it was due to the test or not, because many miscarriages happen naturally at around 12 weeks of pregnancy.

If CVS is done *very early* in pregnancy (before the 8th week after the last menstrual period) there may be an increased risk of a malformation of the limbs. There is no evidence of an increased risk of any malformation at all when CVS is done by an expert after the beginning of the 9th week of pregnancy. Therefore CVS is done only after the beginning of the 10th week of pregnancy, for extra safety. This is why we do an ultrasound examination before arranging the date for the test.

Fetal Blood Sampling

In this test the doctors take **blood** from the fetus, at 18-22 weeks of pregnancy. They use this method when the pregnancy is advanced and the placenta is too far away for CVS. They also use it in rare cases when a DNA diagnosis is not possible.

The obstetrician puts a very thin needle through the tummy and takes a small amount of blood from the baby's cord, where it is attached to the placenta. The needle does not touch the baby itself. The team use an ultrasound scan all the time to guide the obstetrician.



After the test the woman rests for 20-30 minutes in hospital.

It takes about a week to get the result.

How do the laboratory staff test the fetal blood?

Usually they test it by DNA analysis, as for CVS. If this is not possible for some reason, they test it by analysing the baby's haemoglobin directly.

Is fetal blood sampling reliable?

The test is very reliable, but in every medical test there is always a small possibility of a mistake. There is about a 1 in 100 (1%) chance of a mistake.

Is fetal blood sampling safe?

There is no risk to the mother. In about 1 in 100 cases however, a miscarriage will occur. This can happen from a few days to a few weeks after the test.

To keep the risk to the minimum, you should take things easy for one or two weeks after the test, avoiding tiring housework and carrying heavy objects like shopping or children. Avoid sexual intercourse for ten days after the test. If you notice any bleeding or discharge from the vagina, contact the team at once, at the number you have been given at the hospital.

Termination of Pregnancy (Abortion)

If the test shows that the baby is affected, you may decide to end the pregnancy. This is done in one of two different ways, depending on the stage of your pregnancy.

Early termination

This is possible if you are *less than 14 weeks pregnant*. It is quite quick and painless. You come into hospital one evening. The next day you are put to sleep as if you were having an operation. Your womb is emptied through your vagina. You can go home the next day.

A termination does not reduce your chance of having another baby. A few months later you can try again to have a healthy child, and you can have another prenatal diagnosis if you wish.

Late termination

A different method has to be used if the woman is more than 14 weeks pregnant. The obstetrician injects a substance called prostaglandin into the womb. This brings on labour pains and starts a miscarriage. The labour lasts about 17 hours. You can have plenty of pain-killers and some anaesthesia, but of course this is much more upsetting than an early termination.

This type of termination does not spoil your chance of having other pregnancies. After some months you can try again to have a healthy child. But remember prenatal diagnosis can be done early, at about 11 weeks of pregnancy. *As soon as you are pregnant*, ring the number at the end of this booklet to arrange an early visit for counselling.

Part 3.

Other Choices for At-Risk Couples

Pre-implantation diagnosis

People often ask for a better solution than prenatal diagnosis. Now there is promising research on *pre-implantation genetic diagnosis*. If this research is successful, it will allow couples who both carry haemoglobin Lepore to start a pregnancy knowing that the baby will not be affected.

This research is in the very early stages. Even if it shows that pre-implantation diagnosis is possible for most couples at risk for serious haemoglobin disorders, it may not become widely available, because it is expensive. It is likely that it will only be available as a private service for quite a long time.

How can people do pre-implantation diagnosis?

There are several possible ways. They all use in vitro fertilisation methods and DNA analysis. Here we outline one possible method.

The woman has medical treatment to make her produce several eggs. The eggs are collected, and the latest DNA methods are used to identify eggs that do *not* carry a haemoglobin disorder. These eggs are fertilised using the partner's sperm, and two or three are placed in the woman's womb. In young women this gives about a 1 in 3 (30%) chance of a pregnancy. It is necessary to confirm a pre-implantation diagnosis by doing CVS at 11 weeks.

There is as yet very little experience with pre-implantation diagnosis for haemoglobin disorders. At the time of writing (March 1998), world-wide there are four couples with a continuing pregnancy after pre-implantation diagnosis for haemoglobin Lepore major.

Other possibilities

There are other possibilities, but people rarely choose them.

An at-risk couple could *choose to separate*, and each find a partner who is not a carrier (a carrier and a non-carrier cannot have a thalassaemic child). Very few couples who are considering marriage, or who are already married when they discover the risk, make this choice.

They may choose *not have children, or adopt a child*. This is a difficult and very uncommon choice.

They may choose "*assisted reproduction*" to have an unaffected child. There are two ways to do this.

Artificial insemination by donor. The woman may be given sperm from a man who is not her husband. (The "donor" man must be tested and must not carry a haemoglobin disorder.)

Egg donation. The husband's sperm can be used to fertilise eggs taken from another woman. (The "donor" woman must be tested and must not carry a haemoglobin disorder). The fertilised eggs can then be placed in the woman's womb. If the woman becomes pregnant, the baby is her husband's child because he gave the sperm, and her own child because she carries it through pregnancy.

Several attempts are usually needed, and even then there may not be a pregnancy. Assisted reproduction is expensive, and is not generally available on the National Health Service. However, it is the right approach for some couples, and can be arranged privately: ask the counsellor for more information.