



INFORMATION LEAFLET FOR PATIENTS

This leaflet has been especially written for patients who may be about to undergo a Peripheral Blood Stem Cell collection. (This is sometimes called a "PBSC" collection for short.) We hope the leaflet and a discussion with the nursing and medical staff of the Clinical Apheresis Unit (CAU) will help you understand this procedure and what it involves.

What are Peripheral Blood Stem Cells?

The phrase 'stem cells' is used in several different ways by doctors, the television and the newspapers. In this leaflet, 'Peripheral Blood Stem Cells' refers to the immature cells in the bone marrow that grow and divide into mature red blood cells, white blood cells, or platelets.

The bone marrow can be stimulated by injections of a drug called G-CSF, so that some of these stem cells spill over into the peripheral blood that circulates in the veins, from where they can be collected.

What is a PBSC collection?

A PBSC collection is a procedure involving the separation and collection of stem cells from the circulating blood. PBSC collection has now to a great extent replaced the older method of getting stem cells from the bone marrow via a surgical bone marrow harvest.

Why is a PBSC collection necessary?

Your doctor has recommended a high dose of chemotherapy as an appropriate treatment.

The use of high dose chemotherapy dampens down the bone marrow's normal function of making new blood cells for many weeks, during which time you would be prone to infection and bleeding, and need transfusions. To help to reduce these unwanted side effects of the high dose chemotherapy, PBSC can be given to restore bone marrow function. This means that you get the benefits of the high dose chemotherapy while reducing unwanted side effects.

Prior to the use of the high dose chemotherapy, a specific minimum amount of PBSC will be collected and frozen for storage.

After the high dose chemotherapy is given, the PBSC will be thawed and transfused back to you, either through a drip in an arm vein or through your Hickman line. The stem cells migrate to the bone marrow and once there, begin the process of creating new blood cells by growing and dividing into mature red blood cells, white blood cells and platelets.

NATL 006 02 PAGE 1 OF 5





Do I need any tests before having a PBSC collection?

Yes. You will need some blood tests to make sure that you are fit to go ahead with the collection. We also need to assess whether you have been exposed to infectious agents such as HIV, hepatitis, HTLV and syphilis before we are able to collect stem cells from you. This is also done by a blood test. The implications of any abnormal test results will be discussed with you before the tests are done, and you will be told the results of all of these tests, If any of the tests are abnormal, we will arrange for you to be seen by an appropriate hospital specialist, who will then arrange any other tests or investigations that are needed.

What actually happens during a PBSC collection?

The collection is done using a piece of medical equipment called a blood cell separator machine. It uses a centrifuge to separate PBSC from the other blood cells and plasma. The PBSC are then collected into a bag and the other cells and plasma are returned to you. Qualified nursing and medical staff operate the cell separator machine and will monitor you and your medical status at all times.

Before having a PBSC collection, you are likely to receive a prescribed dose of chemotherapy and/or another drug that is a growth factor for blood cells, called G-CSF. This drug causes some of the stem cells in the marrow to be released into the bloodstream, so that they can be collected.

When the Apheresis Unit staff have checked your blood and found that there are stem cells there, and at a good level, a series of PBSC collections will begin.

So that your blood can be processed by the cell separator machine, two drips, or cannulas, will be placed in your arm veins, usually at the elbows. This allows your blood to flow from you through one line and into the machine where it is processed, and then return to you through the other line.

You may already have a thin plastic tube called a central venous catheter (or Hickman line) in a large vein before the collections start. If so, the staff doing the collection may be able to use this as one of the two required lines, and they will put a cannula into an arm vein for the second line.

If you don't already have a Hickman line and the veins in your arms are small and difficult to use, you may need to have a central venous catheter placed in a larger vein by a doctor in advance of the PBSC collection. This will allow blood to be easily removed and returned during the PBSC collection, and is likely that this line will only be needed for the collections. Your doctor will discuss this with you further should a central venous catheter be required.

NATL 006 02 PAGE 2 OF 5





The cell separator machine has to add a drug called "citrate" to the patient's blood as it draws it out, to prevent the blood from clotting in the machine. Some citrate remains with the stored PBSC, but some stays with the blood that the machine is returning to you during the collection. This will not cause you any harm but may cause a temporary lowering of one of the blood salts, the blood calcium. A feeling of numbness or tingling around the lips and fingers, shivering, cramp or a strange taste may be symptoms of a low calcium level. If you get any of these symptoms, you should tell the staff looking after you who can easily treat you with a small amount of calcium in the form of a milky drink or a tablet.

The cell separator machine carries out the PBSC collection in an automated, continuous, and safe manner. The sterile tubing sets and needles are used one time only and then discarded.

Some points which may arise:

- 1. Sometimes to achieve adequate blood flow from the central venous catheter or arm lines, the staff may ask you to change your position in the bed or donor chair.
- 2. Although the cell separator machine removes and replaces only about a teacupful of blood at any one time, this small change in blood volume can make some donors feel dizzy or light-headed. You should tell the staff immediately if you begin to feel uncomfortable.
- 3. The anticoagulant used to keep the blood from clotting might cause a sour taste in the mouth, tingling around the lips, or in the fingers or toes. You should tell the staff immediately if you feel any of these symptoms.
- 4. If you require blood transfusion in the 2 weeks up to and including the PBSC collection days, this blood will be irradiated. This prevents functioning white cells from the transfused blood from being collected along with your own stem cells and interfering with them.
- 5. The PBSC collection procedure can sometimes reduce the number of platelets in your blood. The staff will monitor this and organise a platelet transfusion if required.

Storage of HPC-A cells and discard if no longer needed

After collection, PBSC are stored frozen with a small amount of preservative until required. If a very large number of PBSC have been collected and not all of them are needed for your transplant, the extra PBSC will remain in storage. Sometimes, a transplant has not been planned but your PBSC are collected and stored as a back-up in case they are needed in the future. It may become clear some years in the future that such surplus or back-up PBSC are no longer required as they will not be of benefit to you. If this were to happen, we would like to ask your permission in advance for them to be used for research and development purposes rather than for them to be discarded. This is covered in the consent form you will be asked to sign during your assessment at the CAU.

NATL 006 02 PAGE 3 OF 5





Other questions frequently asked

Q Will there be any pain?

A If you do not have a catheter, insertion of needles may cause some discomfort. Staying relatively still for the time required for the procedure may be uncomfortable.

Q Is PBSC collection a safe medical procedure?

A Greater than 25,000 PBSC collections are performed worldwide each year with few problems. Another one million procedures, which are very similar to PBSC collections, are performed each year on volunteer donors to collect plasma and platelets, again with few problems.

Q Are there any reactions or lasting side effects from the PBSC collection procedure?

A You may feel tired after a PBSC collection and require rest. Side effects during the procedure might include feeling dizzy, light-headed, nauseated, and cold. Some patients may feel tingling in the fingers and around the mouth. These side effects can be quickly and easily treated by the staff.

There may be some side effects from the chemotherapy, similar to the effects you may have had after other chemotherapy. There is no evidence that use of G-CSF is harmful in the long term. There have been 4 reports since 1999 of donors who suffered rupture of the spleen requiring surgery after receiving G-CSF. In most of these cases, the donor took part in contact sport a few days after collection, and so you will be advised to avoid contact sports in the 2 weeks following collection to minimise the chances of this extremely rare complication occurring. Questions about these side effects should be directed to your consultant or the CAU staff.

Q How long does a PBSC collection take?

A This varies from patient to patient. The current cell separator machines used by SNBTS usually perform a PBSC collection in around four hours.

Q Will I be left on my own?

A No. The nursing staff will be there all the time. A doctor will be available nearby throughout the procedure.

Q How often will the PBSC collection need to be done?

A The number of PBSC collections varies, according to the disease being treated, the treatment protocol, and your own response to this. Most patients have 2 collections, and occasionally, 3 are needed. The collection staff will make sure that the required number of stem cells are collected, and in as few collections as possible.

NATL 006 02 PAGE 4 OF 5





Q Can I catch a disease from the supplies being used?

A No. The blood tubing set and needles are sterile, used one time only, and then discarded.

Q What can I do during a procedure?

A You will be advised to have a milky drink and will be given the chance to use the bathroom before the collection starts. You'll be able to read a book or a magazine, watch TV or DVDs or listen to the radio during the procedure.

Q Can I have visitors?

A Yes. There's room for someone to come with you and keep you company during the collection. It's also advisable that there's someone to take you home afterwards.

Q Who can I contact if I have more questions?

A You'll be given a 'contacts' card when you visit the Clinical Apheresis Unit so you can phone the unit if you have any questions after your visit. You can also ask the doctors or nurses looking after you.

NATL 006 02 PAGE 5 OF 5