Eligible Registrants:

● Have fully understood what is involved in donating bone marrow and peripheral blood stem cells (PBSC) (i.e. the content of this pamphlet)

● Healthy adults who are between the ages of 18 and 54

●Weigh at least 45 kg (male) / 40 kg (female)

- The eligible people for the bone marrow/PBSC donation are between the ages of 20 and 55.

* The search for a bone marrow match will begin when the registrant reaches the age of 20.

* The registration of any registrant who has not been subject to the bone marrow/PBSC arrangement will be canceled upon his/her fifty-fifth birthday.

* A registrant who is 54 years old on the day of registration (the blood collection day) and has 10 days or less until he/she reaches the age of 55 may not become subject to the search for a match. This is because it will take up to 10 days to register all the search results, including HLA test results, into the database.

- In some cases, bone marrow/PBSC transplant coordination may not necessarily be carried out, depending on the health condition of the registrant after the donor registration.

- Upon the donation of bone marrow/PBSC, consent from the donor's family is required.

- If the registrant has had hip surgery in past years, the bone marrow cannot be donated.

Please refrain from donor registration if you fall into any of the following categories:

- Currently under medical treatment or on medication (particularly if you have a chronic disease such as bronchial asthma, liver disease, renal disease or diabetes)
- Have histories of malignant tumor, collagen diseases (such as rheumatism arthritis), autoimmune disease, congenital heart disease, myocardial infarction, angina pectoris and apoplexy
- Have (or your family members have) histories of malignant hyperthermia
- Have systolic blood pressure of 151 or greater or 89 or lower, and diastolic blood pressure of 101 or greater
- Have received blood transfusion, are anemic or have blood disease
- Have any infectious disease such as viral hepatitis, AIDS, syphilis or malaria
- Have experienced respiratory distress caused by food or medicine, or have serious anamnestic skin rashes
- Excessively obese (weight (kg) ÷ height(m) ÷ height (m) 30 or greater)

For questions and inquiries, please contact:

03-5280-1789

Japan Marrow Donor Program

7th Floor, 2nd Hirose Bldg., 3-19 Kandanishiki-cho, Chiyoda-ku, Tokyo, Japan 101-0054

TEL: 03-5280-8111 FAX: 03-5280-0101

Donation account/money order: 00130-2-609313

Bone Marrow Donor Registry website: http://www.jmdp.or.jp/

Community site donorsnet: http://www.donorsnet.jp/

Published on April 2012

Please Join the Bone Marrow Donor Registry

CHANCE

A Guide to Joining the Donor Registry

Ministry of Health, Labour and Welfare

Japan Marrow Donor Program

Japanese Red Cross Society

“Expanding the Chance of Survival Through People’s Good Will”

To reach and save a large number of patients who suffer from hard-to-cure blood diseases such as leukemia, and to do so in a fair manner, by transplanting healthy bone marrow/PBSC:

This is the basic principle of the Bone Marrow Donor Registry.

No registrant will be forced into donation in any way, and all information required for decision-making will be provided to him/her.

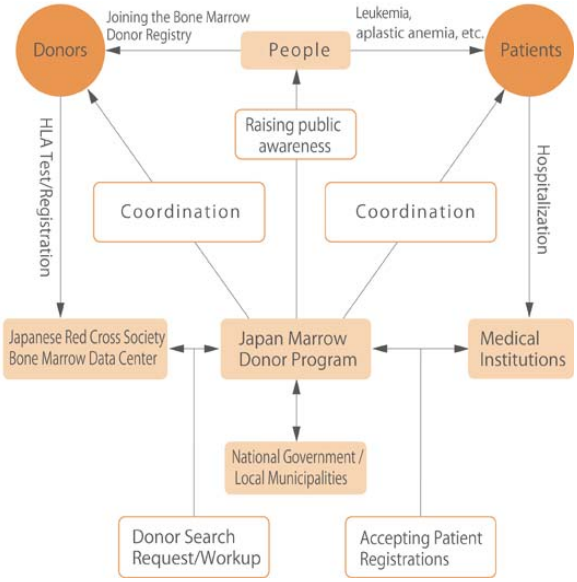
Above all else, the health and safety of donors are the priorities in the Bone Marrow Donor Registry project.

We sincerely hope this pamphlet will help as many people as possible better understand the Bone Marrow Donor Registry, thereby helping them to make the decision to join the Donor Registry and eventually become donors.

Providing a Fair Opportunity for Every Patient Who Wants to Receive a Bone Marrow/PBSC Transplant

System Diagram of the Bone Marrow Donor Registry

The Bone Marrow Donor Registry is a public project implemented mainly by the Japan Marrow Donor Program (JMDP) in collaboration with the Japanese Red Cross Society and local municipalities under the leadership of the national government (i.e. the Ministry of Health, Labour and Welfare). The JMDP coordinates bone marrow/PBSC transplant between the donor and the patient. The Japanese Red Cross Society has established the Bone Marrow Data Centers. All the administrative divisions of Japan, cities and special districts that have public health centers have assigned roles among themselves through these health centers.



Bone Marrow Donor Registry Project

The Role of Each Organization in the Bone Marrow Donor Registry Project

Major Roles of the JMDP

- Raising public awareness toward donor recruitment (PR)
- Accepting registrations of patients who are in need of a bone marrow/PBSC transplant
- Communication and coordination during the entire process up until the provision of the bone marrow/PBSC
- Compensation to the donor in the event that any health damage has occurred during the harvest of the bone marrow/PBSC

(Japanese Red Cross Society)

Major Roles of the Bone Marrow Data Centers

- Donor registration procedures, blood collection for HLA testing
- Execution of HLA testing
- Management of personal information of registrants
- HLA data search based on the request from the JMDP, and report of the results

(The Administrative Divisions of Japan, Cities and Special Districts with Health Centers)

Major Roles of Health Centers

- Raising public awareness toward donor recruitment (PR)
- Donor registration procedures, blood collection for a HLA test

* Please be advised that the term “donor” described above refers to a “person who is willing to donate” the bone marrow/PBSC. It does not refer to a person who actually provides them.

Registration to the Bone Marrow Data Center

Your test and personal information will be registered into the Bone Marrow Data Center. At the Bone Marrow Data Center, the test-result information (HLA test results) and personal information (content of the registration application form) are stored separately and donor privacy is strictly protected.

Location of Registration

(1) Registration procedures (acceptance of application form, blood collection)

Bone Marrow Data Center

(2) HLA test (test-result information management)

(3) Data registration (management of personal information)

(4) Search for a match

(5) Request/provision of registration information

Japan Marrow Donor Program

(6) Starting the coordination

Handling of Registration Information

Sending Confirmation of Registration

Once all the registration procedures have been completed at the Bone Marrow Data Center, the center will send you the “Confirmation of Registration” for the reconfirmation of your address and decision of the registration. Please confirm your name and address described on the Confirmation of Registration. If you find any incorrect information, please contact the applicable data center using the enclosed postcard. When any change occurs to your name, address and/or any other personal information, please contact the Bone Marrow Data Center immediately. The “Change Confirmation” will be sent to you afterward.

If there is any change to your name and/or address…..
Please be sure to notify the Bone Marrow Data Center of such changes.

If your address has not been updated, we cannot inform you about your match (patient). Please follow one of the address-change procedures described below:
Once the procedure is complete, we will mail you the “Confirmation of Registration.”

- Mail us the Change Notification Form enclosed in the Bone Marrow Donor Registry News, which is sent to you twice each year.

* Please be advised that if the Bone Marrow Donor Registry Newsletter has been returned to us due to the failure to notify the Bone Marrow Data Center of a change of address, it will be deemed as “new address unknown," and thus your registration will be put on hold. Once we have received a notification of the new address from you, the pending status of your registration will be canceled.

- Update your address via the Central Bone Marrow Data Center

website: http://www.bmdc.jrc.or.jp/

(Mobile site: http://trk.bmdc.jrc.or.jp/k)

- Contact your nearest bone marrow data center

(For contact information of your nearest bone marrow data center, please refer to page 35.)

Handling of Registered Information

The Bone Marrow Data Center(s) conform to the Privacy Protection Law and therefore strictly control the test-result information and personal information of registrants. Once your HLA test result has been registered in the database, a matching patient will be searched for. After the registration, if it has been found that your HLA type matches that of a patient, you will become a bone marrow/PBSC donor candidate. The Bone Marrow Data Center will then provide your registration information to the JMDP. Additionally, your personal information such as your name and address will be used to send notifications (newsletters) from the Bone Marrow Donor Registry. Your personal information will not be used for any purpose other than as described above.

Basic Knowledge of Bone Marrow/PBSC Transplant

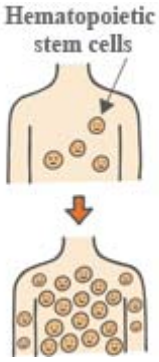
What is a bone marrow transplant?

Bone marrow is a sponge-like tissue present inside the bones, which contains many hematopoietic stem cells that produce white blood cells, red blood cells and blood platelets. A marrow transplant is a treatment that involves the following procedures: The donor undergoes a general anesthesia, after which his/her bone marrow aspirate is harvested by suction. The harvested bone marrow aspirate is then injected into the patient's vein by infusion. During the procedure the spinal cord, which is a thick nerve, will not be punctured with the injection needle.

What is a PBSC transplant?

Normally, only a slight amount of hematopoietic stem cells are present in the peripheral blood (the blood that circulates throughout the body). However, after the injection of the agent that facilitates an increase in the production of white blood cells (G-CSF), hematopoietic stem cells begin flowing in the peripheral blood as well. The agent is then injected for the period of three to four consecutive days until the day of cell harvesting. Once the number of hematopoietic stem cells has increased, the

cells will be harvested from the donor using equipment that separates the blood components. The harvested cells are injected into the patient via the same method used for a marrow transplant.



Major Diseases Subject to Bone Marrow/PBSC Transplant

Leukemia --------- This is an abnormality in the cells that create blood. It is the disease in which transformed blood cells proliferate, but normal blood is not created.

Aplastic anemia ---------- This is a disease in which the functions of the cells that create blood deteriorate, significantly decreasing the number of blood components.

Other diseases that can be subject to the transplant include myelodysplastic syndrome, malignant lymphoma, congenital immunodeficiency and metabolic errors.

Treatment Results of Major Diseases (5-year disease-free survival)

Acute myeloid leukemia ----- [Remission phase] 56% - 38%
[Non-remission phase] 15%

Acute lymphoblastic leukemia ----- [Remission phase] 56% - 23%
[Non-remission phase] 13%

Chronic myelogenous leukemia ----- [Chronic phase] 56% - 45% [Accelerated phase] 40%
[Blast phase] 16%

Severe aplastic anemia ----- [0 - 19 years old] 91% - 66%
[20 - 49 years old] 62% - 41%

The outcomes of the bone marrow transplant treatment will vary according to the patient's age and medical condition.

* Remission phase/chronic phase: These are the phases in which only a small number of leukemia cells is observed as a result of the treatment.

* Accelerated phase: This is the phase in which leukemia cells are gradually increasing.

* Blast phase: This is the phase in which the patient goes into the state of acute leukemia due to a rapid increase in leukemia cells.

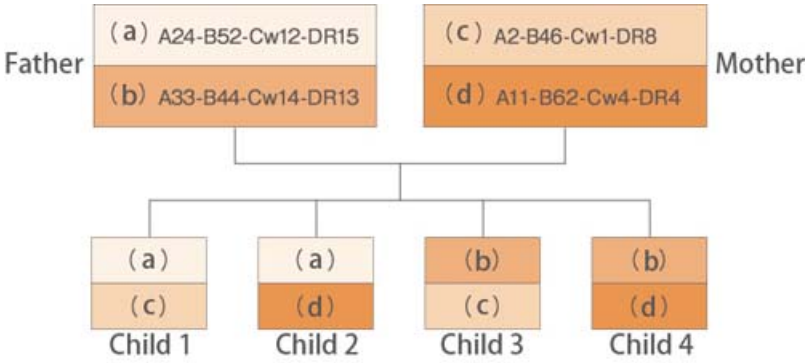
What is the "key point of transplant, HLA types"?

As the A, B, O and AB blood types are found in red blood cells, white blood cells have HLA types. HLA is an abbreviation for Human Leukocyte Antigen, and there are tens of thousands of HLA combinations. In order to transplant the bone marrow or PBSC, it is necessary to confirm the matching levels of the following four HLA loci: A-locus, B-locus, C-locus and DR-locus. The transplant success ratio may decrease, depending on the matching levels, due to complications such as GVHD (graft-versus-host disease) and rejection.

Various HLA Types

A-locus	B-locus		C-locus	DR-locus	DQ-locus	DP-locus
A1	B5	B40	Cw1	DR1	DQ1	DPw1
A2	B7	B41	Cw2	DR103	DQ2	DPw2
A210(2)	B703(7)	B42(12)	Cw3	DR2	DQ3	DPw3
A3	B8	B44(12)	Cw4	DR3	DQ4	DPw4
.	.	.	.	.	.	DPw5
.	.	.	.	.	.	DPw6
.	.	.	.	.	.	
A74(19)	B3901	B78	Cw9(w3)	DR52	DQ9(3)	
A80	B3902	B81	Cw10(w3)	DR53		

Four types of HLA can be considered in a child:



Because a child inherits a half of each locus from each parent, the chance of a complete HLA match between siblings is one-fourth. However, HLA types rarely match between the parent and the child. Between unrelated individuals, the matching chance is only one in several hundreds or one in tens of thousands. That’s why the Bone Marrow Donor Registry is needed, since it recruits donors widely from the general population.

Bone Marrow Transplant and PBSC Transplant Give Enormous Hope to Patients

Overcoming Painful and Difficult Pretreatment

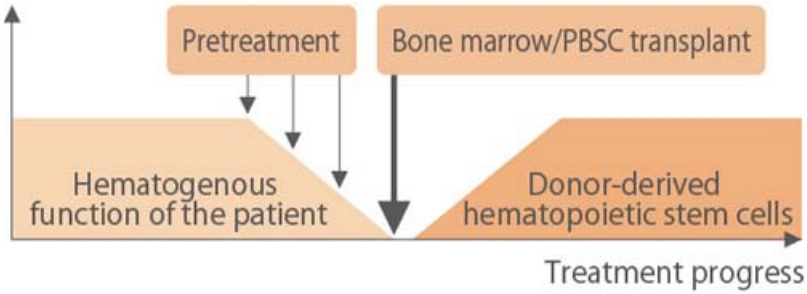
A patient will begin receiving anticancer drug and radiation in preparation for the treatment (i.e. pretreatment) approximately one to two weeks prior to the bone marrow or PBSC treatment. Once the pretreatment begins, the hematopoietic stem cells will be destroyed, thus stopping the production of blood. The patient will undergo a serious do-or-die treatment, enduring violent nausea and hair loss over the whole body.

Moving Forward to a Bone Marrow/PBSC Transplant

On the day of transplantation, the hematopoietic stem cells harvested from the donor are injected into the patient's vein over several hours in the same manner as that of a regular blood transfusion.

From Recovery of the Hematogenous Function to Rehabilitation in Society

The patient will rest in a bio-clean room (a disinfected room) under care in order not to develop any infection. After a while, the transplanted hematopoietic stem cells will begin to produce normal blood. The patient will then be transferred to a regular ward. If the patient demonstrates favorable progress, he/she will be discharged from the hospital and rehabilitated in society.



“Thank You” Messages from Patients

From a transplant recipient who has fully recovered:

To me, the donor has even more significance than God.

When I was a graduate school student with a mission of becoming an architect, I developed myelodysplastic syndrome. If left untreated, the disease would have become aggravated and eventually fatal. The only treatment choice for this disease was a bone marrow transplant. Because I could see the result worsen each time I received a blood test, I even prepared a farewell note for my parents. Therefore, after going through this hardship my bone marrow donor has more significance than God to me. I want to tell my donor, the person who saved my life, “Thank you.” I want to let that person know how grateful I am for being alive, although mere words cannot fully express my appreciation.

(Kaori Tanaka [fictitious name], 28 years old)

From the family of the patient who has fully recovered:

Your courage supported us.

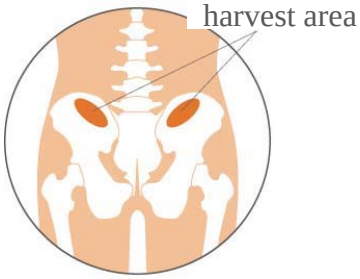
My son was diagnosed with aplastic anemia at the age of two. I was anxious about whether he would have enough strength to endure the transplant procedure, but it turned out to be successful. If the donor didn’t gather his courage, I may not have my son beside me now, showing his affection toward me by calling me, “Mommy, Mommy!” He is now a healthy elementary schoolboy, and he cheerfully goes to school every day. I’m overwhelmed by the feeling of appreciation for being able to spend our time together as a family. I want to keep reminding my son forever that our present happiness is based on the support given by the person with goodwill.

(Yukiko Watanabe [fictitious name], 36 years old)

Bone Marrow Harvest Procedure

Bone Marrow Is Harvested from the Pelvic Bone

The bone marrow aspirate is harvested from the large bone that forms the pelvis, called the “ilium” (the pelvic bone), using syringes. In the operation room, the dedicated needles are inserted through the skin of the donor while he/she lies on his/her stomach in the several areas of the ilium located slightly below the waist, where the belt is worn, at the back side of the pelvis (several tens of locations on the right and left sides of the ilium) in order to harvest the bone marrow aspirate by suction. Usually an amount ranging from 400 ml to 1200 ml is harvested, and the harvest volume is determined according to the weight of the patient. Most of the harvesting of bone marrow is conducted under general anesthesia, and a period of one to three hours in required in order to complete the procedure.



Progress After the Harvest

Donors are usually discharged in one or two days after the procedure. Many of them can immediately return to normal daily life. After being discharged from the hospital, the coordinator in charge will continue to follow up by phone in regard to the donor’s health condition. The donor will quickly regain the normal amount of bone marrow aspirate that had decreased due to the harvesting procedure.

Although donors may occasionally experience the following symptoms due to the harvesting of bone marrow, these symptoms will quickly disappear in most cases:

Pain ---- Once the anesthesia has worn off, the donor may occasionally experience pain in the areas where the needles were inserted (puncture wounds). The level of pain varies, depending on the person. The pain typically lasts from one to seven days. There have been a few cases in which the pain was prolonged over a month.

Other symptoms such as fever ---- The donor may occasionally experience symptoms such as fever from 37℃ to 38℃, sore throat, nausea and general malaise. These symptoms will usually improve in a day or two.

After harvesting ---- Depending on the donor's physical constitution, slight needle marks may be left on the skin. These marks will usually disappear in three to six months.

PBSC Harvest Procedure

PBSC Is Harvested from the Arms

The agent (G-CSF) that increases the number of white blood cells will be injected to the donor for the period of three to four days prior to the harvesting procedure. On the fourth or fifith day after the start of the G-CSF administration, the hematopoietic stem cells, which have begun flowing in the peripheral blood (which circulates throughout the body), are harvested using dedicated equipment. Needles are inserted into the arms*, and only the hematopoietic stem cells are removed from the blood, whereupon the rest of the blood is returned to the donor. If the amount of harvested PBSC is not sufficient, a second harvesting procedure will be conducted the next day. It requires approximately three to four hours to complete the harvesting procedure, and during the procedure the donor cannot move his/her arms.

* If the PBSC cannot be harvested from the arms, they may occasionally be collected from the blood vessels of the donor's groin.

Progress After the Harvest Procedure

As a general rule, donors will stay in the hospital overnight after the procedure and will be discharged the next day. Many donors can immediately return to normal daily life. Subsequent to the discharge, the coordinator will continue to follow up by phone in regard to the donor's health condition.

Although donors may occasionally experience the following symptoms due to the PBSC harvest, they will quickly disappear in most cases:

Various symptoms caused by injection ---- Temporary symptoms include bone pain (lower back pain, joint pain, etc.), malaise, headache, chest pain, sleep disruption, anorexia, nausea, vomiting, palpitation and rash. Pain can be eliminated by analgesic drug.

Various symptoms during harvesting ---- Due to the anticoagulant agent administered to prevent the coagulation of harvested blood, the donor may experience numbness in the limbs and/or around mouth. In many cases these symptoms will disappear by calcium administration.

After harvesting ---- Occasionally, the number of blood platelets may decrease. If this is the case, appropriate treatment will be administered. Furthermore, although the skin color of the areas where the needles were inserted may become bluish, it will usually disappear in one to three weeks.

Volunteer for Lives − Donor Registration Begins from 2ml of Blood Collection

Each year at least 2,000 patients need bone marrow or PBSC transplants from unrelated individuals.
In order to save as many people as possible, it is essential to have as many people as possible join the Donor Registry.
It only takes a blood collection of 2 ml to join the registry.
For patients who long for matching donors, your registration could represent the chance for survival.

Flow of Donor Registration

If you are interested in joining the Donor Registry, please read this pamphlet thoroughly. Once you have fully understood the information, fill out the “Bone Marrow Donor Registry Registration Form” and then sign the form. Please bring the signed form to your nearest registration counter, or to one of the donor registration meetings held nationwide.

* The registration form can be downloaded from the Bone Marrow Donor Registry’s website or picked up from a registration counter.

* Donor registration is free.

* For the locations of registration counters in each district of Japan, please refer to the list provided from pages 24 through 35 of this pamphlet.

* For the details of donor registration meetings, please refer to the Bone Marrow Donor Registration website: http://www.jmdp.or.jp/

Registration takes approximately 15 minutes. The donor registration procedure can be conducted at any registration counter.

* You may have to wait a while during peak hours.

Approximately 2 ml of blood will be collected from the vein of the arm in order to test the HLA type (the white blood cell type). The test is free.

* No test will be conducted to confirm your blood type (A, B, O or AB type), the presence of infections or your

health condition.

* A DNA test will be conducted on the collected blood only to confirm the HLA type. No other genetic testing will be conducted.

* You will not be notified of your HLA type.

* The sample blood (blood/DNA specimens) will be discarded after the completion of the required testing. However, DNA specimens will be partially used in order to maintain the HLA test quality as well as to evaluate the reagent used for HLA testing once the donor's identity has been made unidentifiable.

* Please refer to page 7 for more information about HLA types.

Subsequently, the Confirmation of Donor Registration will be sent to you from the Bone Marrow Data Center of the Japanese Red Cross Society. The process of searching for an HLA match between registrants and patients will be conducted on a regular basis.

* Search for a match for patients who have made a request for the search from overseas countries via the JMDP is also conducted.

* In collaboration with the bone marrow donor registries of the U.S.A., Korea, Taiwan and China, the JMDP participates in the BMDW (the Bone Marrow Donors Worldwide), in which countries throughout the world participate.

The Delivery of Your Goodwill -- From You to the Patient

Bone Marrow/PBSC Donation Process

1. When you become a donor candidate:

Once your HLA type matches that of a patient, the JMDP will notify you that you have been chosen as a donor candidate. Please fill out the questionnaires regarding your decision, the intentions of your family pertaining to your decision, your health condition and schedule. Please be advised that, depending on your current health condition, you may not be able to participate.

2. Coordination and Confirmation Test

The coordinator in charge of communication and coordination with the donor candidate will schedule your confirmation test. Upon confirmation testing, the coordinator will meet with you in person to explain the details of the bone marrow/PBSC donation, and the doctor will explain the donation from a medical viewpoint and ask about your medical condition. The doctor will also confirm whether there is any bone marrow/PBSC harvesting procedure that you may not agree to undergo. Once it has been confirmed that you haven't changed your decision regarding donation, your blood will be collected in order to check your health condition.

3. Important Commitment and Final Consent

Once you have been chosen as a donor candidate, the coordinator and doctor will confirm your (or your family's) final decision on donation in the presence of a witness (final consent). The signature of the final consent is an important commitment. Once the final consent is given, you cannot overturn your decision of donation. After the final consent, the donation date will be coordinated and a hospital will be arranged.

4. Health Examination

Approximately one month prior to the bone marrow/PBSC harvest, a detailed health examination will be conducted by the doctor at the hospital (designated by the JMDP) so that the harvest procedure can be safely performed. You will receive the Donor Notebook prior to donation.

When Donating Bone Marrow

5. Blood Collection for Autologous Transfusion

In order to minimize anemia after the harvesting procedure, your blood will be collected and stored one to three weeks beforehand.

6. Bone Marrow Harvest

You will stay in the hospital for three nights and four days. The donor will be hospitalized one to two days before the harvesting procedure and will receive a health examination and explanation.

When Donating PBSC

5.Injection of the Agent (G-CSF) to Increase the Production of White Blood Cells

Either during the three to four days of visiting or staying in the hospital, G-CSF will be injected to the donor. After the injection, the hematopoietic stem cells will begin to flow in the peripheral blood.

6. PBSC Harvest

The PBSC harvest procedure will be conducted on the fourth or fifth day after the G-CSF injection. Even if you receive the injection as an outpatient, as a general rule you will stay in the hospital one night and two days for the harvest procedure. If the amount of PBSC is not sufficient, a second harvest will be performed the next day.

◎ No hospitalization fee will be charged for bone marrow donation or PBSC donation.

◎ It can be expected that, for the time being, bone marrow donation may be the only choice of harvesting due to the status of the patient, donor and hospital.

7. Your Bone Marrow/PBSC Will Be Transferred to the Patient

The harvested bone marrow/PBSC will be delivered to the hospital, where the patient is waiting, and transplanted into the patient there.

8. You Will Be Discharged Within a Few Days*

You will be discharged from the hospital in a few days after the harvesting procedure, and then you can return to normal daily life. After the discharge from the hospital, your health condition will be followed up until you are fully recovered from the harvesting procedure. Your coordinator will check your condition over the phone, or a health examination will be conducted one to four weeks after the discharge.

* The length of the hospitalization varies according to the method of harvesting.

Donor Safety and Peace of Mind Are Our Priority

Although donor safety is the number-one priority in a bone marrow/PBSC transplant, in the past there were cases in which the donor's health was damaged. In any case, the donor recovered after receiving treatment and eventually returned to his/her normal daily life. The JMDP urges the harvesting facilities throughout Japan to take extreme care in order to prevent such accidents.

Compensation System in Case of Health Damage

In the event the donor's health is damaged during the marrow/PBSC harvest procedure, the compensation up to 100 million yen will be paid to the donor. In case of death, compensation of 100 million yen will be paid to the donor's family impartially. For any sequela, compensation from 3 million yen to 100 million yen will be paid depending on the severity. The JMDP has performed more than 10,000 bone marrow harvests since 1993, the year in which the first harvest was performed, until the end of March 2011. Of those cases, the hospital insurance (for both hospitalization and hospital visits as an outpatient) and similar insurances were applied to 111 cases.

■ Adverse events in Bone Marrow Harvest (data of unrelated cases)

----------Major Cases of Health Damage in Past----------

Onset of Acute Hepatitis C After Bone Marrow Harvest (March 1998)

As a result of the investigation, it was reported that there was a possibility that the donor may have become infected during the hospital stay for the purpose of the bone marrow donation.

Development of Retroperitoneal Hematoma After Bone Marrow Harvest (September 2000)

The donor complained of lower abdominal pain, and a retroperitoneal hematoma was confirmed. It was pointed out that the needles used for the harvesting procedure may have penetrated through and thus damaged the blood vessel, thereby causing major internal bleeding.

The Case in Which Pulmonary Fat Embolism Was Suspected (August 2003)

In this case the decrease in the oxygen saturation concentration in the donor's blood was observed. As a result of the test, pulmonary fat embolism was suspected.

In order to provide accurate safety information to the public, we at the Bone Marrow Donor Registry strive to release as much information as possible. For more details, please visit our website: http://www.jmdp.or.jp/

There Has Been No Fatal Case in The JMDP.

Three fatal cases during the harvesting of bone marrow that occurred to donors (two cases between blood relatives, one case between unrelated individuals) have been reported in overseas countries. In Japan one such case (between blood relatives, in which case the donor-patient match was not coordinated by The JMDP was reported in 1990. This is because, even though the donor is healthy, there is a slight possibility that emergency treatment may need to be performed during anesthesia as with a standard operation. Therefore, medical experts will conduct the bone marrow harvest with extreme care, taking every possible precaution.

■Adverse events in PBSC Harvest (data of blood relative cases)

----------Major Cases of Health Damage in Past----------

Blood Relative PBSC Donor's Cases Reported to the Japan Society for Hematopoietic Cell Transplantation (from April 2000 till March 2005)

The Case in Which Angina-Like Attack Occurred During the PBSC Harvest

The donor with past history of hyperlipidemia felt tightness in her chest during the harvesting procedure. It was pointed out that this symptom may have been induced by convulsion caused by hypocalcemia (i.e. numbness and similar symptoms that can manifest due to the anticoagulant administered to the donor to prevent the coagulation of collected blood).

The Case of Gouty Attack/Acute Exacerbation of Gallstone Cholecystitis: G-CSF Injection Was Suspected as the Likely Cause

On the second day of the G-CSF injection period, a gouty attack manifested. It was pointed out that this may have been related to the fact that the number of white blood cells had increased due to the injection of G-CSF. Moreover, acute exacerbation of gallstone cholecystitis (chronic) was observed once the injection period had ended. It was therefore suspected that the inflammation was aggravated by G-CSF injection.

The Case in Which Interstitial Pneumonitis Occurred on the Third Day of G-CSF Injection

On the third day of the G-CSF injection period, fever, an increase in blood gas levels and a decrease in oxygen concentration levels were observed in donors who had histories of hypertension and hyperlipidemia.

Information on adverse events in blood relative PBSC donors is provided by the Japan Society for Hematopoietic Cell Transplantation on its website: http://www.jshct.com/

There Has Been No Fatal Case Involving Blood-Relative PBSC Donors in Japan

In overseas countries, eleven fatal events in blood-relative PBSC donors have been reported. These events occurred within 30 days after PBSC harvesting, and it has been concluded thus: “Although the correlation between the death and PBSC harvest is unclear, it cannot be denied completely.” It was pointed out that, in any case, there were certain risk factors such that the donor was old or he/she had an underlying disease (but no fatal case involving unrelated donors has been reported). In Japan, PBSC harvesting has been performed under the strict observation of the qualification standards and guidelines stipulated by the Japan Society for Hematopoietic Cell Transplantation based on the cases in overseas countries. Therefore, no fatal event or severe sequela has ever occurred, either during the harvest procedure or 30 days after the harvesting procedure.

Results of Bone Marrow Donor Questionnaires

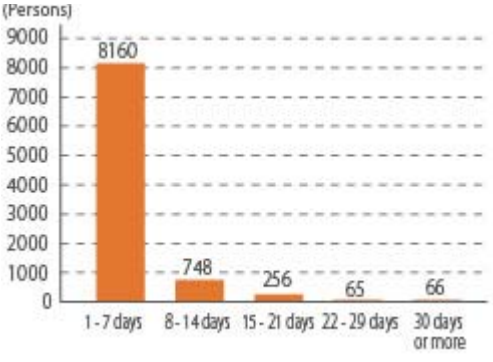
The results of questionnaires on various aspects of bone marrow donations, such as the length of hospital stay and honest impressions regarding bone marrow donation conducted on bone marrow donors, are shown below. Please refer to these results when you make a decision regarding donation.

* The results of questionnaires conducted on PBSC donors will be posted once the data has been aggregated.

Length of Hospital Stay for Bone Marrow Donors (as of the end of March

Approximately 30% of the 103 people stayed in the hospital for seven days or longer due to the situation in the hospital where the harvest procedure was conducted. For 40% of the remaining 70%, the length of hospital stay was longer than initially planned due to the donor’s health condition. Furthermore, regarding 30% of the above remaining 70%, harvesting was postponed, thereby extending the hospital stay.

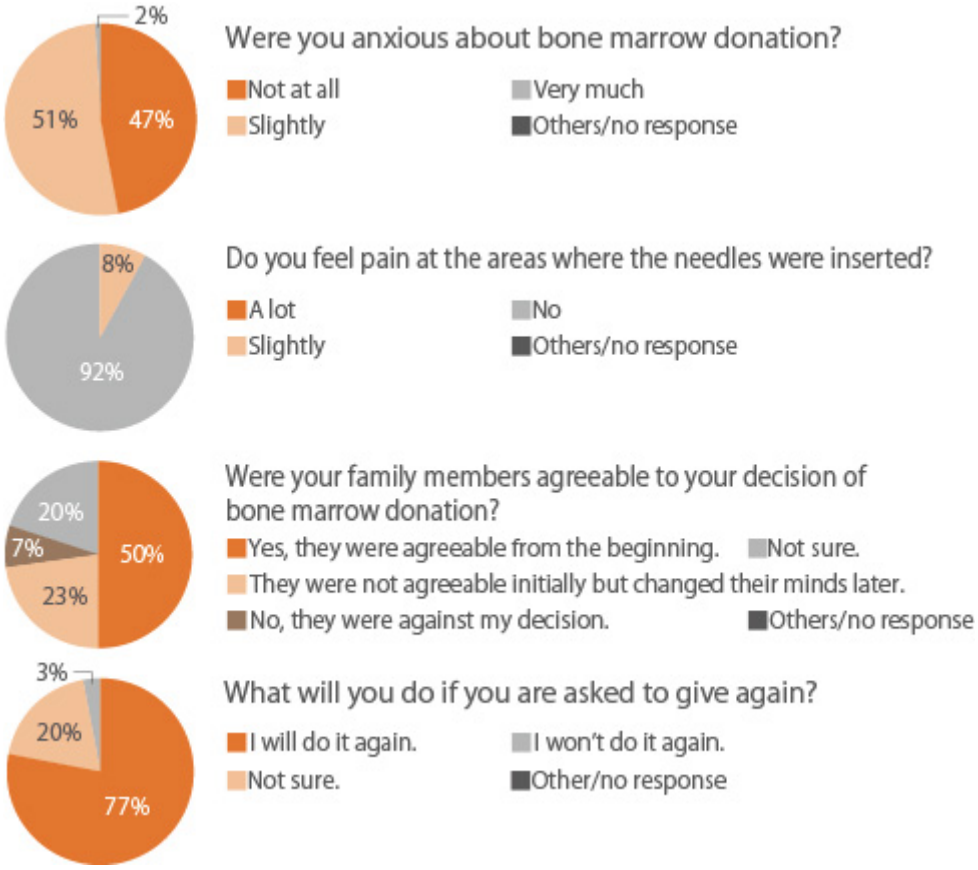
Number of Days Required for Returning to Daily Life



The above graph shows the number of days required for donors to return to normal daily life after the day of harvesting (determined as “0”). Please consider this as a rough guideline for your return to daily life after the bone marrow harvest procedure.

Results of the Questionnaire Conducted Three Months After Harvesting (the number of responses: 7972)

Target: Bone marrow donors during the period from May 1, 1993 to December, 2009



Stories of Donor Experiences

Story of Bone Marrow Donation Experience

My second son was diagnosed with leukemia when he was five years old. Fortunately, his HLA type matched that of my eldest son, so my second son was able to receive the bone marrow and became healthy. Because of this experience I grew eager to help patients who were in need of bone marrow as well as their families, so I joined the Donor Registry and donated my bone marrow two years after the registration. Because it was my first time to receive general anesthesia, I was a bit nervous at first. However, I don't remember anything that happened after I fell asleep. Once the anesthesia wore off, I felt dull pain around my lower back. To be honest, when the urethral catheter was removed I felt indescribable pain. Although I felt a loss of strength in my lower back immediately after the procedure, I was able to walk normally again in two days or so.

(Yoshiyuki Osawa [fictitious name], 40 years old)

Story of PBSC Donation Experience*

My sister developed malignant lymphoma when she was fifteen, so I donated my PBSC to her. We were four sisters altogether, but only my HLA type matched hers. Although there was another choice of bone marrow donation, they recommended the PBSC harvest because it would be more suitable for my sister's condition. The G-CSF injection didn't particularly hurt, but the needles used for PBSC harvesting were quite thick so it was painful. Although it took about four hours to complete the harvest procedure, it didn't really bother me because I was watching DVD movies. I couldn't move immediately after the harvest because I was extremely tired. Although my whole body was numb and I felt dizzy because of the agent administered for the procedure, these symptoms were only temporary and disappeared quickly.

(Emi Sakashita [fictitious name], 32 years old)

* The donation was from a blood relative.

Please Feel Free to Contact Us with Any Questions Regarding Donor Registration

Tel: 03-5280-1789

* For other Q&As, please visit the website of Bone Marrow Donor Registry: **http://www.jmdp.or.jp/**

Q. Can donors choose a patient?

A. No, they can't. Because the Bone Marrow Donor Registry coordinates everything fairly, a donor is not permitted to choose a particular patient.

Q. Can donors meet their matching patients in person?

A. In order to operate the Bone Marrow Donor Registry without bias and protect privacy for donors and patients, donors are not permitted to meet their matching patients in person. However, donors are permitted to send letters no more than twice within a year after the bone marrow/PBSC donation, as long as the donor's identity is not revealed.

Q. Can a donor refuse the bone marrow/PBSC donation?

A. Joining the Donor Registry and donating bone marrow/PBSC are totally up to an individual's free good will. Even after the registration, the individual's decision to donate will be repeatedly confirmed at each stage, and he/she can say "no" anytime during this confirmation stage. However, once the final consent has been signed the donor cannot reverse his/her decision.
Upon donor's signing the final consent form, the patient will begin preparation for the transplant procedure. This means the patient will lose the function to produce blood due to chemotherapy and radiotherapy. To take back your decision of donation would be fatal to the patient.

Q. Why does the bone marrow/PBSC donation require family consent?

A. If the donor's family were to press the donor to overturn his/her decision of donation immediately before the bone marrow/PBSC transplant, it would put the patient into a catastrophic situation. In order to avoid that worst-case scenario, it is necessary to obtain family consent. Please understand that we only obtain consent from the donor's family prior to the donation procedure out of care toward patients. As a general rule, the meeting for final consent must be conducted in the presence of the donor's parents if he/she is single or the donor's spouse if he/she is married. If you don't have anyone who would fall under either category, or if you are in an inevitable situation, please consult your coordinator once the coordination process has begun.

Q. Is there any cost involved in joining the Donor Registry?

A. No cost (such as testing and hospitalization costs) is involved in bone marrow/PBSC donation. However, you will be responsible for the transportation expense that may be incurred by your donor registration.

Q. Can I join the Donor Registry during my pregnancy or after childbirth?

A. You may join the Donor Registry during your pregnancy. However, from the viewpoint of the health and safety of the donor (pregnant woman) and her child, you cannot make a donation of the bone marrow/PBSC. Once a year has passed after childbirth, you can make a donation.

Q. I understand that people who have stayed in Europe for a certain period of time can't give blood. Can't they join the Donor Registry either?

A. They may join the Donor Registry. With regard to blood donation, for example, if the person stayed in England longer than a month, he/she will be asked to refrain himself/herself from donating the blood. However, such a restriction on the Bone Marrow Donor Registry registration was abolished in June 2005.

Q. Is there any compensation for absence from work?

A. Because the bone marrow/PBSC donation is based on your free will, you will receive no compensation even though you have to be away from work. If you wish, the certificate for the bone marrow/PBSC donation will be issued for certain government/municipal offices and companies that implement the "bone marrow donor special vacation program."

Q. Why is a genetic test required in order to join the Donor Registry?

A. The test is required for the investigation of the donor's HLA type in order to improve the result of bone marrow/PBSC transplant. No other gene region except for HLA type will be investigated. Although the sample blood (blood/DNA specimens) will be discarded after the completion of the required testing, DNA specimens will be partially used in order to maintain the HLA test quality as well as to evaluate the reagent used for HLA testing, once the donor's identity has been made unidentifiable.

Q. Is there any chance that I won't be able to donate my bone marrow/PBSC once I've joined the Donor Registry?

A. Even though you were healthy upon registration, you may not be able to donate your bone marrow/PBSC depending on your health condition when you become a donor candidate. Furthermore, if the registrant is deemed ineligible during the process after the confirmation testing due to any health reason, the donor coordinator of the JMDP will inform the registrant of the cancellation of the registration after discussing the matter with the registrant.

Q. What is the communication method when an HLA match has been found?

A. Once you have been chosen as a donor candidate, the "Explanatory Materials" and "Questionnaires" will be sent to your home from the JMDP, which is in charge of donor coordination. Subsequently, a coordinator will meet with you in person to explain the details of the bone marrow/PBSC harvest, and the doctor will explain about the transplant from a medical viewpoint and ask you about your medical condition. If your decision of donation has not changed, a confirmation test will be conducted. Please consult with your coordinator or the JMDP office regarding any concerns or questions during this stage.

Q. What about the cancellation or pending procedure of donor registration?

A. Donor registration can be either canceled or put on hold anytime you want. Please notify your nearest Bone Marrow Data Center. Please notify if you have to leave Japan for a long-term overseas post. The donor registration will then be put on hold during your absence. When you return, please undertake the procedure to cancel the pending status. Furthermore, please consult with us for the pending status of your registration during your pregnancy and child-rearing period.

(For contact information of your nearest bone marrow data center, please refer to page 35.)

Q. What is going to happen once I reach age 55?

A. For those who did not become subject to coordination, the registration will be canceled automatically.

Q. What should I do if my address has changed due to moving or other reasons?

A. If your address changes at any point after the registration, please follow one of the

address-change procedures described below:

- Mail us the Change Notification Form enclosed in the Bone Marrow Donor Registry News, which is sent to you twice each year.
- Update your address via the Central Bone Marrow Data Center website.
- Contact your nearest bone marrow data center.

If you faile to notify the Bone Marrow Data Center of a change of address, we cannot inform you about your match (patient). (Please be advised that if the Bone Marrow Donor Registry Newsletter has been returned to us due to the failure to notify the Bone Marrow Data Center of a change of address, it will be deemed as “new address unknown," and thus your registration will be put on hold. Once we have received a notification of the new address from you, the pending status of your registration will be canceled.)

* Central BoneMarrow Data Center website: http://www.bmdc.jrc.or.jp/

Q. Can I freely choose the harvesting method?

A. The final decision of the harvesting method will be made by the patient. However, the donor will be asked if he/she does not agree with either method. Because the patient will be notified of the donor’s preference, the harvesting method that the donor doesn’t prefer will not be undertaken. In the event the patient’s expectation and donor’s preferred method don't match, coordination may be terminated. Depending on the patient, donor and hospital situations, bone marrow donation may be the only choice for harvesting.

Q. Which harvesting method causes the least burden on the donor?

A. Comprehensively speaking, there is no difference in the donor’s burden between the two harvesting methods. According to the questionnaires conducted on donors in the U.S., subjective symptoms such as pain began to manifest in bone marrow donors after the harvesting procedure. For PBSC donors, such symptoms began to emerge after the initiation of G-CSF injection. However, the intensity and duration of the pain were roughly equal between the two methods. Regarding long-term side effects, as the result of a Japan/Europe joint investigation it has been concluded that there is no difference between the two methods concerning the probability of serious complications.

	Bone Marrow Harvest	PBSC Harvest
G-CSF Injection	Not performed	Performed
Autologous Blood Collection	Performed (Not required in some cases)	Not performed
General Anesthesia	Performed	Not performed
Length of Hospital Stay * Depending on the facility	Approx. 3 nights 4 days	If hospitalized only for harvesting: 1 night and 2 days – 2 nights and 3 days If hospitalized from the first day of the injection period throughout the procedure: 4 nights 5 days – 6 nights 7 days
Number of Harvesting Facilities	Approx. 170	Several tens of facilities (It will be increased to approximately 100 facilities in the future.)
Number of Visits to the Facility for Interview, Test and Harvesting	About 7 times	If hospitalized only for harvesting: About 8 times If hospitalized from the first day of the injection period throughout the procedure: about 5 times

Q. Which harvest method is better for patients?

A. Although the bone marrow transplant and PBSC transplant use the same transplanting technique, which is infusion, each method has its own advantages and disadvantages. For example, the bone marrow transplant tends to be chosen for aplastic anaemia and child patients, and the PBSC transplant tends to be used for patients with advanced-stage leukemia or infectious diseases as well as with patients of advanced age. The characteristics of each method will be taken into account when the method of harvesting is selected.