number and types of cells, to make sure that it is sterile, and to learn other things that may be important to the transplant.

Using a Central Line

Sometimes the needles used in the apheresis process are too big for a donor's arm veins. In the NMDP's experience, this happens in about 18% of women and 3% of men. If it is thought that the needles will be too big for your arm veins, you may be asked to have a blood-drawing tube called a "central line" placed in a larger vein in your body. The choice to use a central line may be made at your complete check-up (when your veins will be checked) or it could be made on the day you donate.

Placing a central line requires a surgical procedure under local anesthesia. A doctor does this in a hospital. In this case, your collection will also take place in the hospital and, if you donate over two days, you will need to stay in the hospital the night between donations.

Before a central line is placed, you will be asked to sign a separate consent form that explains the risks of central line placement. You are free to say no to having a central line placed. If you choose not to have the central line placement, you may be asked to donate bone marrow instead.

3. Following Up After Your Donation

After your donation, you will be called on the phone and asked questions about how you are feeling physically. These calls will start two days after the donation and will be made each week until you feel you are back to normal. You will be called again at one month, six months and then yearly after that.

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A list of visits and calls is given in the following table (an X marks what will happen on each visit/call):

Visit/Call	Risks Assessed	Filgrastim Shot Given	PBSCs Donated	Blood Drawn
Screening check-up	X			X
Preparation, Day 1	X	X		X
Preparation, Day 2	X	X		
Preparation, Day 3	X	X		
Preparation, Day 4	X	X		
First donation, Day 5	X	X	X	X
Second donation[a]	X		X	X
2 days after donation (call)	X			
1 week after donation[b] (call)	X			
1 month after donation (call)	X			
6 months after donation (call)	X			
Yearly visits after donation (call)	X			

[a] If needed, based on size of the recipient.

[b] Calls will continue weekly until complete healing from donation is reported.

4. What are the possible risks of donating PBSCs?

Cautions: You should not take aspirin or drugs with aspirin in them while getting filgrastim and for two weeks after PBSC donation without a doctor's approval. During the PBSC donation, your platelet count may be lower because platelets are collected with the PBSCs. Taking aspirin when your platelet count is lower may increase your chance of bleeding.

You should not take filgrastim if you are pregnant. You should not become pregnant while taking the drug. This is because filgrastim may cause serious problems for an unborn child. It is recommended that you wait to try to get pregnant until the drug is no longer in your blood. Both men and women should wait at least 48 hours after the last dose of filgrastim to conceive a child.

Mothers should stop breast feeding and not store breast milk while receiving filgrastim. This is because it is not known whether filgrastim is passed into breast milk. It is recommended to wait 48 hours after the last dose of filgrastim before resuming breast feeding.

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The following table lists the risks for receiving filgrastim and donating PBSCs.

BLOOD DRAW	
Risks	*Some people have:* • Bruising where the needle was put in • Fainting *Very few people have:* • An infection where the needle was put in

GETTING SHOTS OF FILGRASTIM	
Risks	*Most people have:* • Pain from the shot • High white blood cell count White blood cell counts usually return to normal levels within a few days to a few weeks after you stop receiving filgrastim. • Aching pain in bones while getting the filgrastim The aching bone pain is usually relieved by acetaminophen (Tylenol™) or ibuprofen (Motrin™, Advil™). If you have pain that is not relieved by these drugs, you should contact the Donor Center Coordinator, _____ at ( ) _____, and the dose of filgrastim may be reduced. *Some people have:* • Headaches • Muscle aches • Being tired • Nausea and vomiting • Trouble sleeping *Very few people have:* • Allergy symptoms (all symptoms usually go away within two or three days after stopping filgrastim): – rapid heart rate – dizziness – shortness of breath – itching or rash • Lowered platelet count Filgrastim may cause your platelet count to be lower than normal. Platelets help stop bleeding. Two out of 1400 NMDP donors had very low platelet counts that needed to be watched closely. Although one donor went into the hospital for this, neither had symptoms from the low platelet count and both got well.

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	Your platelet count will be measured on Day 5, before the first PBSC donation. You will be told if your platelet count is too low. In this case, depending on the true value of your platelet count, a doctor will talk with you about other options, such as to: – Monitor your platelet count during the PBSC donation. – Shorten the donation process. – Delay the donation for a day. – Cancel the PBSC donation. – Ask you to consider a bone marrow donation. – Ask you to consider some other course of action that is okay with you. • There is a small (about 1 in 1,200) risk of being hospitalized for observation of side effects from the filgrastim (for example bone pain, nausea). • For a very small number of people filgrastim may cause a decrease in oxygen that can affect the heart, causing shortness of breath and chest pain. The NMDP is aware of three NMDP donors who have had these symptoms. These symptoms were not related to a heart attack. However if you experience pain coming from your chest on the days of filgrastim injections, or during or after your PBSC donation, you should tell your doctor immediately. Also, if you have a family history of heart problems, you should discuss this with the doctor during your physical exam prior to your PBSC donation. • There is a small (about 1 in 5,000) risk of bleeding in the head. The NMDP is aware of two NMDP donors who had bleeding in their head shortly after completing their filgrastim injections and PBSC donation. It is not clear the bleeding was related to filgrastim; both donors had other factors that may have played a role in the bleeding. Both donors recovered. The major symptom from bleeding in the head is a severe headache, sometimes with other symptoms like numbness, muscle weakness, confusion or changes in vision. If you experience a severe headache during the days of filgrastim injections or during or after your PBSC donation, you should tell your doctor right away. • There is a small (about 1 in 10,000) risk of pain and bleeding from the spleen. The NMDP is aware of five non-NMDP donors who had pain and bleeding from the spleen while getting filgrastim. In four cases the spleen was taken out by surgery. All five got well. Symptoms of bleeding from the spleen are pain in the upper left side just below the rib cage. **If you feel pain in this area you should contact your Donor Center right away.**

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	• Healthy individuals are at risk for developing cancer, including leukemia, lymphoma or other blood diseases throughout their life time. Filgrastim stimulates normal blood cell growth. In some patients with cancer or abnormal blood cells, it has been shown to stimulate leukemic blood cells. It is unknown whether filgrastim increases or decreases an individual's risk of developing cancer. Based on available data from healthy people who have received filgrastim, no long-term risks have been found so far. The data being collected during follow-up will help establish if there are any positive or negative long-term effects from receiving filgrastim. **If you think you are having any serious or unexpected symptoms, contact the Donor Center right away at ( ) _____.**

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DONATING PBSCs	
Risks	*Most people have:* • Pain and bruising where the needles are put into the arms • Lowered platelet count. In addition to collecting PBSCs, the blood cell separator also collects platelets. Platelets help stop bleeding. If your platelet count after the first donation is too low, the second donation may be cancelled. Platelet counts usually return to normal levels within two to four weeks after collection of PBSCs. *Some people have:* • Lightheadedness • Nausea • Numbness and tingling To prevent clotting, your blood will be mixed in the machine with a liquid called an "anticoagulant" during the PBSC collection. When the blood is returned to you the anticoagulant can cause numbness and tingling of the fingertips or around the mouth. If you feel numbness and tingling, you must tell the nurse running the machine. These symptoms are easily treated with calcium, but if not treated could progress to muscle cramps. *Very few people:* • Faint due to short-term low blood pressure. • Experience chills during the process. • Experience severe bleeding in the arm. • Have a loss of blood from a breakdown of the blood cell separator machine. If the machine does breakdown you could lose about 1½ cups of blood. This is unlikely to cause you harm. • There is a small (about 1 in 1,200) risk of being hospitalized for observation of side effects from the donation (for example lightheadedness, nausea).

Additional Risks

Donating for a recipient can cause strong feelings, especially if the transplant does not succeed. These feelings may range from stress during the process to great joy or feeling sad after the donation. By donating for this recipient, you are doing all you can to help them. You cannot control the success of the transplant, or whether the recipient lives or dies. You are not personally responsible for the outcome.

You may be asked to donate again for the recipient if the donated cells do not grow in the recipient or if the recipient's disease is not cured. If you are asked to donate again, you are free to say no.

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5. What do I do if I am injured in this study?

The risk of serious injury in this study is thought to be small. If you are injured, treatment (to include first aid, emergency treatment and other needed care) will be on hand for you. The NMDP will pay for this treatment. Please call your Donor Center Coordinator right away at ( ) _____ if you are injured.

In the case of an injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

6. Do I have to agree to be in this study?

No, it is up to you if you want to participate in this study. If you decline to participate, the NMDP will not remove you from the Registry unless you ask for this to be done. Your decision to decline participation will not change your relationship with your Donor Center or the NMDP. There will not be any penalty or loss of benefits. Your decision to decline participation will not affect your right or access to health care or any other service that you are entitled to receive at your Donor Center.

7. Are there alternatives to being in this study?

Yes. If you decide you do not want to take part in this study, you may be asked to donate bone marrow for the recipient.

8. How long will I be in this study?

You will be in this study as long as you are willing. Each year you will be asked to answer some questions about how you are feeling physically.

You will be informed of any new finding which may affect your decision to continue your participation in this research study.

9. Can I stop being in this study?

Yes, you may stop taking part in this study at any time. If you want to withdraw, you are asked to tell your Donor Center Coordinator. Your choice to stop will not change your relationship with your Donor Center or the NMDP. There will not be any penalty or loss of benefits. Your choice to stop will not affect your right or access to health care or any other service that you are entitled to receive at your Donor Center.

If you choose to stop before donating PBSCs:

It is important you know that if you decline to donate after the intended recipient begins to get treatment to get ready for the transplant, he or she will most likely die. If you have any questions about this statement, please contact your Donor Center Medical Director.

10. Will it cost me money to be in this study?

No. There is no cost to you for the check-ups, collecting the PBSCs or the follow-up after your donation.

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11. Will I be paid to be in this study?

No. You will not be given any payment for being in this study.

12. Are there rewards to being in this study?

You will not receive direct payment or reward for being in this study. But, this study may help future recipients in need of transplants, as well as future donors.

13. How does the NMDP use donor data?

As part of your participation in this study, your demographic and health information will be entered into the NMDP Research Database. The NMDP collects these data on all donors. This helps the NMDP make sure it is doing the best job it can and learn how to improve where needed.

By signing this consent form, you allow _____ (Donor Center) to give the NMDP your demographic information (for instance: gender, age and ethnic background) and health information that was taken as part of the donation process (for instance: results from infectious disease testing and the physical exam and information on healing from the donation). This information will be used by the NMDP to evaluate operation of the Registry, to report to its funding agencies, and to conduct research. In addition, people doing studies approved by the NMDP may use this information for research.

This authorization does not have an expiration date. You have the right to cancel this authorization at any time by notifying the NMDP in writing that you are canceling the authorization. The address for the NMDP is 3001 Broadway Street NE, Suite 500, Minneapolis, MN 55413. If you cancel this authorization, any identifiable health information will be removed from the NMDP Research Database. If you cancel your authorization, this will not affect your right or access to healthcare or any other services you are entitled to receive at _____ (Donor Center).

14. Will my health information and surveys be kept private?

We will do our best to make sure that the personal information in your donation record is kept private. We cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Groups that may look at and/or copy donation records for research, quality assurance and data analysis include:

- The NMDP and its affiliates
- The NMDP Institutional Review Board (IRB)
- The National Institutes of Health (NIH) and other government agencies, like the Food & Drug Administration (FDA), involved in keeping research safe for people.

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Steps used to keep your data private are:

- To label your data with a nine-digit identification (ID) number instead of your name. This ID number is chosen at random and does not contain any identifying information about you.
- To limit who sees your data.
- To keep your data in locked files.
- To destroy all papers when they are thrown away (for instance, by shredding).
- To use special, protected computer systems.

15. Who can I contact with questions or concerns about this study?

The doctors for this study are:
Dr. _____ _____ ( ) _____
(Donor Center Medical Director)

Dr. John P. Miller, MD, PhD (800) 526-7809
(NMDP Medical Director)

For questions about your rights while taking part in this study, please contact Roberta King, Institutional Review Board (IRB) Administrator, at (800) 526-7809

16. Donor/Participant's Signature (NMDP DID: _____)

I have been given a copy of all 14 pages of this form. I have read it, or it has been read to me. I have been given the opportunity to ask questions and have had my questions answered. I agree to take part in this study.

_____ _____
Donor/Participant's Signature *Date*

_____
Donor/Participant's Name Printed

NATIONAL MARROW DONOR PROGRAM® INSTITUTIONAL REVIEW BOARD
CONSENT FORM APPROVAL DATE:
MAY 21, 2009
Do not sign this form after the Expiration date of: **May 14, 2010**

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered.

_____ _____
Counseling Healthcare Professional *Date*

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Use of an Interpreter: *Complete if the subject is not fluent in English and an interpreter was used to obtain consent.*

An oral translation of this document was administered to the subject in _____ (name of language) by an individual proficient in English and _____ (name of language). See the attached short form addendum for documentation.
(Short form addendum may be requested from NMDP)

_____ _____
Interpreter's Signature *Date*

_____
Interpreter's Name Printed

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ATTACHMENT A

WHY DO I NEED THESE BLOOD TESTS?

Standard Blood Tests
Tests are done on your blood to make sure it is safe for you to donate PBSCs or bone marrow. Any increased risk might mean that you would not be allowed to donate, or that only one of the two methods of donating would be advisable for you. These tests also protect the recipient getting your donation.

Blood Tests for Diseases
Your blood will be tested for infectious diseases including HIV, Hepatitis and West Nile Virus.

If your check-up or blood tests reveal anything that is not normal, you will be told. The NMDP or your Donor Center may also be required by law to notify your state public health agency if you test positive for Hepatitis B, Hepatitis C, the virus that causes AIDS (HIV) or other infectious diseases.

Check for Sickle Hemoglobin
Your blood will be tested for sickle hemoglobin. This test may result in genetic information that is new to you. There have been reports of severe reactions to filgrastim in persons with sickle cell disease. If your blood test is positive for sickle hemoglobin, you will not be able to participate in this study. However, you may still be asked to donate bone marrow for this recipient.

Pregnancy Test
If you are a woman of childbearing years, you will be required to take a pregnancy test. You must not donate bone marrow if you are pregnant. You must not take filgrastim if you are pregnant. This medication could cause serious problems for an unborn child. You must make sure that you do not get pregnant while taking filgrastim and for 48 hours after the last shot.

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ATTACHMENT B

DEFINITIONS

Anesthesia is the giving of a drug or drugs designed to relieve pain and/or cause loss of consciousness.

Apheresis is a process where a machine divides blood into its separate parts. Blood is removed from one arm of the donor, passed through the machine, which separates out the needed type of cell(s), and returns the remaining blood to the donor. Over time, the donor's body naturally replaces the blood cells that are removed.

A **Central Line** is a sterile tube put into one of the larger veins, usually in the groin area (femoral vein), the neck area (internal jugular) or just below the collarbone (subclavian vein).

Demographic Information are facts about the part of the country where you live; what sex, race and age you are, and what ethnic group(s) you belong to. These facts help people study the health data. It does not include your name.

Filgrastim is a drug that causes the bone marrow to produce more blood forming cells than usual. When these cells go into the bloodstream they are often called peripheral blood stem cells (PBSC). They can be collected from the bloodstream. Filgrastim is also called "G-CSF" and marketed in the U.S. as Neupogen®. Filgrastim has been approved by the Food & Drug Administration (FDA) to collect PBSCs from recipients getting transplants of their own cells. It is also approved to treat recipients with cancer getting chemotherapy, for recipients getting bone marrow transplants and for recipients with diseases causing very low white blood counts.

An **Institutional Review Board (IRB)** is a group of people who review research methods and results to protect your rights and safety.

PBSC are "peripheral blood stem cells." This is another term for the blood forming cells circulating in your bloodstream that can be taken by a machine.

Platelets are special blood cells that help you stop bleeding by making clots.

Blood forming cells are cells found in the bone marrow and bloodstream that rebuild your blood, bone marrow and the immune system.

A **Syringe** is used to inject or withdraw a fluid. It has a hollow needle to break the skin and fluid is either injected into the body through the needle or fluids such as blood are withdrawn from the body.

A **Teaspoon** is a common unit of measurement. One teaspoon is equal to about five milliliters. There are three teaspoons in a tablespoon, 48 teaspoons in a cup.

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【資料 2 】

Bone Marrow Transplantation (2001) 27, 917–923
© 2001 Nature Publishing Group All rights reserved 0268–3369/01 $15.00
www.nature.com/bmt

Peripheral blood stem cells

Donating stimulated peripheral blood stem cells *vs* bone marrow: do donors experience the procedures differently?

GE Switzer[1,2], JM Goycoolea[3], MA Dew[2,3,4], EC Graeff[5] and J Hegland[5]

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Summary:

As the demand for undifferentiated stem cells for the treatment of leukemia and other cancers has increased, new methods for their collection have been developed. One of these new methods, allogeneic peripheral blood stem cell (PBSC) donation, involves the administration of a granulocyte colony-stimulating factor (G-CSF, filgrastim), and a 1–2 day apheresis collection procedure. Our goal in the current study was to examine donors' psychosocial and physical experiences of PBSC *vs* marrow donation. Potential participants included 80 donors from the National Marrow Donor Program (NMDP) who donated a second time between 1991 and 1997. All of these donors had previously donated marrow. A final cohort of 70 donors (25 PBSC and 45 marrow) participated in a retrospective questionnaire study of their donation experiences. In general, all second-time donors reported low levels of concern about the physical consequences of donation. However, PBSC donors were more likely to have postponed the decision to donate a second time. Despite their reservations, PBSC donors reported fewer donation-related side-effects than did marrow donors. Finally, PBSC donors reported that marrow donation was more physically difficult, time-consuming, and inconvenient, and that they preferred PBSC to marrow donation. *Bone Marrow Transplantation* (2001) **27**, 917–923.

Keywords: stem cell; bone marrow; donation

Since the early 1980s, allogeneic bone marrow transplantation has become an increasingly popular treatment option for persons with leukemia or other blood-related diseases for whom other forms of therapy have been ineffective.[1,2] The most commonly used procedure for collecting bone marrow from donors involves the aspiration of marrow from the iliac crests of the pelvis. Although the long-term physical costs of bone marrow donation are likely to be small, the process of marrow aspiration does pose a significant health risk to the donor and almost always involves some physical side-effects. The physical risk of the operation itself includes the small possibility of severe life-threatening complications[3] – or even anesthesia-related death.[4] In addition to an overnight hospital stay, donors typically require a day or two at home to recuperate and a few weeks before they feel totally recovered.[5]

The potential for adverse physical effects, and the increasing demand for the undifferentiated stem cells found in bone marrow, have led the medical community to develop and test new methods for collecting stem cells. In the past decade, the donation of peripheral blood stem cells (PBSCs) has been proposed as an alternative to the aspiration procedure. A central advantage of PBSCs is that they can be collected from the donor on an outpatient basis.[6,7] In order to obtain the volume of peripheral blood stem cells needed for transplantation, a hematopoietic growth factor (G-CSF; filgrastim) is typically administered to the donor on 4–5 consecutive days before the donation of stem cells. Potential side-effects of G-CSF include bone pain, headache, body aches, fatigue, nausea/vomiting and difficulty sleeping.[8–10] PBSC donation with the use of G-CSF has been used successfully for autologous marrow transplants, and on a more limited basis for allogeneic transplants.[11,12] Early evidence from both the European and North American transplant communities indicates that PBSC donation might have advantages for both donors and recipients. For donors, the collection of PBSCs is performed on an outpatient basis without the risks of surgery and general anesthesia, and involves virtually no known severe or enduring post-collection side-effects.[6] On the other hand, PBSCs administered to patients may engraft more quickly than stem cells collected from bone marrow and yield shorter patient recovery times.[8,13,14]

The National Marrow Donor Program (NMDP) – the largest registry of unrelated donors in the world – began collecting G-CSF-stimulated stem cells in 1994 using the PBSC procedure only among donors who were donating a second time to the same recipient whose initial engraftment had failed; second time marrow donations began in 1991. In July 1999, the NMDP broadened the range of donors who could donate stem cells using the PBSC procedure to include first time donors. Although the psychosocial consequences of decisions about donating marrow and the donation process itself have been well documented,[15,16] there have been no systematic investigations of donors' experiences of bone marrow *vs* PBSC donation. NMDP donors who donated a second time from 1991 to 1997 are ideally suited for such a comparison given that nearly 40% of this group underwent the PBSC collection procedure; all primary donations in this group were bone marrow donations. In 1997, we began an investigation designed to compare the physical, psychosocial, and pragmatic consequences of donating PBSCs *vs* bone marrow among these second-time donors.

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Received 12 December 2000; accepted 12 February 2001

Materials and methods

Study participants and procedure

Between 1991 – when the first second-time donation was performed through the NMDP – and 1997, a total of 80 NMDP donors donated a second time. All of these donors previously had donated marrow. Of these 80 second-time donors, 30 donated PBSCs and 50 donated marrow. The decision about which product (marrow or stimulated stem cells) to request for the second donation was made by transplant centers based on the medical condition and requirements of the recipient; donors themselves did not select a particular procedure. A final cohort of 79 second-time donors – one donor belonged to a donor center which declined to participate in the study – were asked to participate in a retrospective study of their donation experiences.

Questionnaires, consent forms and cover letters explaining the study were mailed to donor centers where donors were registered. Donor coordinators at each center addressed and mailed the packets to the donors. Contact with donors was mediated by donor centers in this manner to protect donor confidentiality. Donors who did not respond to this initial mailing within 2 weeks were contacted by telephone by the donor center, and after 2 more weeks, received a second full packet with a revised cover letter. A total of 70 of the 79 donors (88%) – 25 of 29 PBSC donors (86%) and 45 of 50 marrow donors (90%) – completed and returned their questionnaires. The difference in response rate of PBSC and marrow donors is small and not statistically significant minimizing the possibility of bias due to differential responding.

Measures

In addition to donor demographic characteristics, we also assessed the physical, psychosocial, and pragmatic consequences of donation by each method. The physical consequences of donation were evaluated in terms of both the perceived health effects of donation and the actual side-effects experienced. To measure perceived health effects, respondents were asked questions such as 'Do you think that your second donation has had any long-term effects on your health?' (dichotomized as yes and maybe *vs* no) and 'How often do you worry about the overall effects of the second donation procedure on you?' (dichotomized as often, sometimes, and seldom *vs* never).

To measure specific side-effects, respondents indicated whether or not they had experienced any of a list of side-effects, including both general side-effects such as fatigue, headaches and problems sleeping, and more specific side-effects such as lower back pain and pain where the needles were inserted.

Psychosocial issues in donation were assessed with items concerning the decision to become a second-time donor, others' reactions to the possibility of a second donation, and global comparisons of first and second donations. Included among the decision-making items were questions such as 'How hard a decision was it for you to decide whether to donate the second time?' (very, somewhat, and a little, *vs* not at all hard) and 'Did you postpone thinking about the big decision to actually donate the second time?' (definitely, somewhat, and a little, *vs* not at all). Others' reactions to donation were assessed with questions like 'Was there anyone who suggested any problems about your second donation or who tried to discourage you from donating?' (yes *vs* no) and 'After the second donation was there anyone who praised you or said good things about the fact that you donated a second time?' (yes *vs* no).

Finally, global comparisons items included the following: 'Which would you say was more emotionally stressful – your first donation or your second donation?' (first, second, or equally stressful) and 'Overall, which would you say was more difficult – your first donation or your second donation?' (first, second, or equally difficult).

Pragmatic consequences of donation were assessed by providing respondents with a list of potential donation inconveniences, including time missed from work, income lost from work, travel time, travel costs, arranging child care, changing personal plans, waiting to hear if he/she was a donor, waiting on medical staff, waiting for donation to happen. Respondents indicated which items were inconveniences for them. In addition, donors were also asked to indicate how many hours they missed from work and home activities.

Finally, PBSC donors only were asked to compare the two donation procedures in terms of their physical and emotional difficulty, the time required, and the amount of inconvenience. In addition, PBSC donors were asked which donation method they and their family would prefer for them if they were asked to donate again. They were also asked which procedure they would recommend for a family member about to donate. Respondents were asked to choose one of the two procedures, or to rate them as equal.

As noted previously, responses to all items were dichotomized for the purpose of analysis. A series of chi-square analyses to detect differences in the proportions of each donor group endorsing a particular physical, psychosocial, or pragmatic consequence of donation was performed.

Results

Donor demographics

We examined whether second-time donors who donated PBSCs differed demographically from those who donated marrow. As is evident in Table 1, the majority of second-time donors were Caucasian, married, relatively highly edu-

Table 1 Donor demographic characteristics

Characteristic	Marrow (n = 45)	PBSC (n = 25)	Total (n = 70)
2nd donation date (range; mean)	3/91–11/96; 3/95*	7/94–8/97; 11/96*	3/91–8/97; 6/95
Age, M (s.d.)	38 (12)	38 (16)	38 (14)
% Female	44	52	47
% Ethnic minority	7	16	10
% Married	62	72	66
% College degree	58	56	57
% Homemaker/student	27	24	26
% Christian	84	68	79

*Donation dates were converted to metric years for statistical analysis.
*t-test for mean difference in donation date; $P \leq 0.05$.

cated, and Christian; there were approximately equal numbers of men and women donors. The only significant demographic difference between groups was that PBSC donors, on average, had donated more recently than had marrow donors ($t(69) = 2.32$, $P \leq 0.05$).

Physical consequences of donation

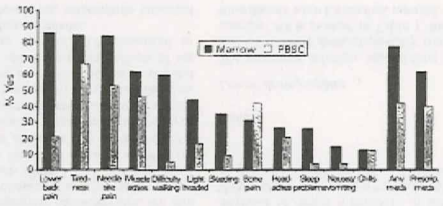
In general, all second-time donors reported low levels of concern about physical consequences of donation (Table 2). Less than 10% were worried (1) about their current health state, (2) that the donation procedure had damaged their health or, (3) about the long-term health effects of having donated. Only the most general health-related question, 'How often do you worry about the overall effects of the second donation procedure on you?' received a higher level of endorsement; 21% of all donors said that they had at least some health concerns. There were no statistically significant differences in the percentages of PBSC and marrow donors who endorsed these items.

Despite low levels of reported physical health concerns about second donation, a substantial proportion of donors reported specific donation-related side-effects. As indicated in Figure 1, depending on the donor group, some side-effects (eg lower back pain, tiredness, needle site pain, difficulty walking) were experienced by more than half of donors. There were significant differences in the proportions of bone marrow vs PBSC donors who experienced many of the side-effects. Bone marrow donors reported experiencing more lower back pain, pain at the needle entry site, difficulty walking, light headedness, bleeding, and difficulty sleeping. PBSC donors reported experiencing more bone pain than did marrow donors, but this difference was not statistically significant. Figure 1 also indicates that well

Table 2 Perceived health effects and psychosocial issues in second donation

Item	Marrow (n = 45)	PBSC (n = 25)	Total (n = 70)	χ^2 value
Perceived health effects of donation				
% Worried about damage to own health	4	4	4	0.00
% Worried about overall effects of donating	20	24	21	0.15
% Currently worried about own health	4	8	6	0.40
% Worried about long-term health effects	11	4	9	1.04
Psychosocial issues in second donation				
Decision-making in second donation				
% Knew right away would definitely donate again	87	80	84	0.54
% Not at all hard to decide to donate 2nd time	80	76	79	0.15
% Postponed decision	4	20	10	4.32*
% Disappointed if could not donate 2nd time	96	88	93	1.38
% Consulted friends or relatives	51	72	59	2.90
Others' reaction to donation				
% Discouraged from donating a 2nd time	33	36	34	0.05
% Encouraged to donate a 2nd time	43	16	33	5.30*
% Criticized for having donated a 2nd time	14	8	12	0.49
% Praised for having donated a 2nd time	87	100	91	3.64
Comparing first and second donations				
% Felt totally prepared for 2nd donation	78	76	77	0.03
% More worried about health before 2nd donation	7	20	11	2.82
% 2nd donation was more emotionally stressful	18	28	21	1.00
% Thought 2nd donation was more difficult	20	28	29	0.58

*$P \leq 0.05$.



χ^2 value: 28.60*** 2.91 8.14** 1.71 20.24*** 5.32* 5.64* 0.66 0.29 5.18* 1.98 0.01 9.00** 1.67

*$P \leq 0.05$ **$P \leq 0.01$ ***$P \leq 0.001$

Figure 1 Physical side-effects of second donation.

over half of donors reported using pain medications to treat these side-effects, and that marrow donors were significantly more likely than were PBSC donors to have taken pain medications. Marrow donors tended to be more likely to have used prescription medications than were PBSC donors, but the difference was not statistically significant.

Psychosocial consequences of donation

In terms of decision-making about second donation, both marrow donors and PBSC donors showed a high level of commitment towards donating. As indicated in Table 2, 79% of donors said that their decision was not difficult, 84% knew right away that they would donate again, and 93% would have been disappointed if they could not donate again. Despite this, PBSC donors were significantly more likely to postpone the second donation decision (chi-square (70) = 4.32; $P \leq 0.05$).

Others' reactions to the second donation were almost universally positive – more than 90% of donors were praised for having donated again, and only 12% were criticized. About a third of all donors had been discouraged by others from donating a second time. The only variable concerning others' reactions on which marrow and PBSC donors differed significantly was that PBSC donors were less likely to have been encouraged by others to donate a second time (chi-square (70) = 5.90; $P \leq 0.05$).

All donors were asked to compare their first and second donation experiences, and only a minority of donors rated the second donation experience as more psychologically distressing. Fewer than a quarter of donors felt that the second donation was more stressful or difficult, or caused them to worry more about their health than the first donation. Three-quarters of donors reported feeling totally prepared for the second donation.

Pragmatic consequences of donation

Nearly 40% of donors reported missing more than 20 h each from work and home activities as a result of the second donation. All donors reported missing some time from work and home activities. Bone marrow donors were more likely than PBSC donors to report missing more than 20 h from work and home activities although this difference was not statistically significant. However, the difference between the two donor groups was statistically significant for missing more than 20 h from home activities (49% vs 20%; chi-square (70) = 5.66; $P \leq 0.05$). As shown in Figure 2, about a third of donors reported that the time missed from work was inconvenient, and bone marrow donors were more likely than PBSC donors to report that missing work was inconvenient (chi-square (70) = 6.81; $P \leq 0.01$). Other commonly reported concerns among all donors were the need to change personal plans as a result of the donation, and travel time to and from the donor center. There were no other statistically significant differences between marrow and PBSC donors.

Comparing the donation procedures

PBSC donors were asked to compare the two donation procedures across four dimensions – physical, emotional, time required, and inconvenience – and to express a preference for a donation method if they would need to donate again in the future. As indicated in Table 3, a majority of PBSC donors found their marrow donation more physically and emotionally stressful, time-consuming, and inconvenient. A greater proportion of PBSC donors also reported that they and their families would prefer PBSC donation to marrow donation if they were needed to donate in the future, and that they would recommend PBSC rather than marrow donation to a family member.

Discussion

As the need for stem cells from unrelated donors increases, scientists will continue to develop innovative methods of harvesting and transplanting stem cells that attempt to minimize the risk to donors, and maximize the potential for successful engraftment in the recipient. PBSC donation is an alternative to marrow donation that has been used for the past several years in second-time donors (and recently approved for first-time donors). The central goal of this

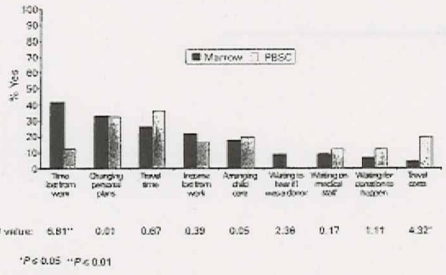


Figure 2 Inconveniences of second donation.

Table 3 Donation method preference among PBSC donors ($n = 25$)

Item	Marrow donation	PBSC donation	No preference/ Both equally
Which donation method was harder physically?	68[a]	28	4
Which donation method was more emotionally stressful?	49	29	22
Which donation method required more of your time?	76	12	12
Which donation method was more inconvenient?	68	16	16
If you needed to donate again, which method would you prefer?	20	60	20
Which method would your family and friends prefer for you?	9	49	26[b]
Which donation method would you recommend to a family member?	16	60	24

[a]Numbers in the table are percentages.
[b]Sixteen percent of family members and friends would not want the donor to donate again.

study was to investigate the second-time donation experiences of unrelated bone marrow vs PBSC donors. It should be noted that second donation experiences and the experiences of unrelated donors, in general, may differ from first donation experiences and those of related donors. Second-time donors have already experienced the donation process once, and they may also be aware that because their recipient needs a second donation, he/she must be in poor health. Related donors' donation experiences are likely to be distinct emotionally and psychologically given that they are more intimately connected to the recipient. Thus, further research will be necessary to ascertain the generalizability of our findings to these other donor groups.

Overall, a very high proportion of all donors in this study reported a strong commitment to donating a second time. However, PBSC donors were more likely than marrow donors to postpone the decision and to be concerned about their health before the second donation (although not statistically significantly). They were also less likely to be encouraged by others to donate a second time. It is probable that PBSC donors and those close to them were cautious about this donation procedure because they were aware that the use of filgrastim and the collection of stem cells from the peripheral blood was a relatively new procedure. It also seems likely that marrow donors might have been less concerned about the second donation procedure because they had already undergone the procedure once and were well prepared for what to expect. At the time these data were collected only a small proportion of PBSC and marrow donors were at all concerned about their current health, or about the longer-term health effects of having donated. In addition, PBSC donors did not report elevated health concerns relative to marrow donors indicating that the slightly higher levels of pre-donation concern among PBSC donors did not persist after donation.

Physically, marrow donors reported having much more difficulty with donation than did PBSC donors. Overall, more than 80% of marrow donors reported lower back pain, tiredness, and pain at the site where the needles were inserted. In addition, a significantly greater proportion of marrow donors as compared to PBSC donors reported experiencing a variety of post-donation side-effects. The most commonly reported side-effects among PBSC donors were tiredness, needle site pain, and muscle aches, and the only side-effect reported more frequently by PBSC donors than by marrow donors was bone pain. The additional fact that a greater proportion of marrow donors also reported using pain medications also supports the idea that marrow donation produces more intense physical reactions.

Aside from the physical side-effects of donation, a relatively low proportion of donors reported other inconveniences of the donation process. As might be expected,

marrow donors, who generally have an overnight stay in the hospital and a 5–6 day recovery period, missed more time from work, and rated this missed time as more inconvenient than did PBSC donors. The main inconveniences for PBSC donors seemed to involve logistic concerns such as changing personal plans and the travel time to the donor center. This may reflect the fact that many PBSC donors must travel to a donor center or hospital for 5–6 sequential days to receive an injection and then to donate stem cells. The fact that much lower proportions of donors endorsed other inconveniences suggests either that the donation process does not really inconvenience donors, or that donors find these inconveniences small relative to the importance of donation.

Finally, PBSC donors, who had undergone both procedures, reported that they found their marrow donation more physically and emotionally stressful, time-consuming, and inconvenient, and that they would prefer PBSC donation if they needed to donate again. Although these findings are based on a relatively small number of PBSC donors, they are consistent with other results presented here, including the lower levels of physical side-effects among PBSC donors as compared to marrow donors.

In summary, although our overall findings from this investigation must be interpreted cautiously because of the cross-sectional and retrospective study design, they do indicate that second-time donors generally felt prepared for the donation and unconcerned about the health effects of the donation procedure. These findings are consistent with our other prospective longitudinal studies of first-time marrow donors who also report positive donation experiences. Perhaps the most striking findings of this study are the large differences in the physical side-effects of the two donation procedures, and PBSC donors' clear preference for PBSC rather than marrow donation. Although it is still imperative that any possibility of longer-term adverse health consequences of filgrastim be ruled out, these findings suggest that PBSC donation is likely to be preferred by future donors.

Acknowledgements

This work was supported in part by a contract with the National Marrow Donor Program, Minneapolis, MN.

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■PBSC の凍結について

1.凍結を認める事例

凍結は、移植施設から書面で事前の申請があり、NMDP が承認し、ドナーセンターとドナーの同意を得られれば認めている。患者の状態が悪化した場合は採取日を再調整することがほとんどだが、どうしても移植施設・ドナーセンター・ドナー間で再調整ができない場合は、凍結が申請されることもある。

2.申請の方法

・移植施設は、凍結の計画と医療上必要とする理由を書面にて申請。(資料　3　)
・NMDP のサーチコーディネーションユニットのマネージャーがチェックしメディカルディレクターが承認。
・ドナーセンターとドナーの同意は必須。
・ドナーには凍結しても使用されない例があることも説明し同意を確認。
※非常にまれなケースでは、ドナーセンターから凍結の提案がされることもある。それが移植施設にとって困難であれば、ドナーセンターとドナーは可能な採取日を模索する。

3.凍結の後

・NMDP のサーチコーディネーターが計画通り使用されたか追跡する。
・計画通りに使用できない場合、いつまでにどうするか等新しい計画を確認する。
・患者が亡くなって使用できなかった幹細胞の扱いについては NMDP が定めた方針に則って移植施設が決める。
・その方針では、廃棄することや、匿名化したうえで研究試料として研究に使用することを認めている。
・ただし研究に使用する場合には、ドナー・ドナーセンターの同意に加えて、移植施設の審査委員会の承認を得なければならず、NMDP へ書面で報告しなくてはならない。

【参考情報】(資料 4)

a.申請の理由	患者理由	68%
	ドナー理由	10%
	その他 ・　バックアップがない ・　ベッドの空きがない ・　骨髄への移行ができない ・　スタッフの問題 ・　スケジュール等	22%
b.凍結実施数	BM	23/876 (3%)
	PBSC	70/1938 (4%)
c.使用されなかった数	・凍結した BM・PBSC 合わせて 93 例中 9 例 (10%)	

	・採取全体（2814 例）の 0.3% ・使用しなかった理由は患者が死亡（3 例）、あとの 6 例は不明	
d. 生着 1)	あり	64/84 例（76%）
	なし	9/84 例（11%）
	不明	11/84 例（13%）

1) 生着に関する解析は公式なデータフォームを使用して行われたものではない。

4. 凍結実施場所

・NMDP では採取施設が細胞処理等を行うことを認めていない。凍結は移植施設の責任下で行う。

5. 細胞数が多く、その一部しか移植に使用しない場合は、移植施設が残りを凍結することを認めていると聞いているが、保存期限や品質管理など条件はあるか。

・廃棄に関するポリシー（PBSC、BM 共通）。（資料　1　）

【参考情報】

①採取したプロダクト（すべて）に関する方針

移植に使用しなかったプロダクトは凍結保存、廃棄、匿名の研究に使用する。

・採取した後に予定移植日が延期または中止された場合、2 日以内に NMDP へ書面で報告する。

・ドナーから提供されたプロダクトすべてを凍結する場合、2 日以内に NMDP へ書面で報告する。凍結したプロダクト、またはその一部を後で移植使用してもよい。

・凍結したプロダクトを移植したり廃棄する場合は、2 日以内に NMDP へ書面で報告する。

・移植に使用しなかったプロダクトを匿名の研究に使用する場合は、前もって NMDP へ書面で報告する。NMDP はドナーセンターへ報告し、ドナーセンターがドナーの承諾を得なくてはならない。ドナーが承諾しなければプロダクトを廃棄しなくてはならない。また、匿名の研究ではドナーが特定されないようにし、移植施設の審査委員会の承認を得て、国の規定に従わなくてはならない。

②一部使用しなかったプロダクトや試料に関する方針

移植後に一部残った試料やプロダクトは凍結保存、廃棄、匿名の研究に使用する。

・一部残った試料やプロダクトを凍結保存する場合、NMDP へ報告する必要はない。

・一部残った試料やプロダクトを廃棄したり、匿名の研究に使用する場合、NMDP へ報告する必要はない。

・匿名の研究に使用する場合には、ドナーが特定されないようにしなくてはならない。移植施設の審査委員会の承認を得て、国の規定に従わなくてはならない。ドナーの承諾を得る必要はない。

【資料 3 】

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Policy for Disposition of Donor Products, Cord Blood Units and Specimens

This Policy pertains to the disposition of:

1. Entire donor products (*e.g.*, marrow, PBSC, therapeutic cells, whole blood, etc.) that were collected and not infused into the intended recipient;
2. Entire cord blood units selected for infusion and shipped to a transplant center that are not subsequently infused into the intended recipient; and
3. Partial unused products (*e.g.*, marrow, PBSC, therapeutic cells, cord blood, whole blood, etc.) left over after infusion and unused donor specimens (*e.g., blood for clinical testing*) left over after clinical testing.

I. *Entire Donor Products (non-Cord Blood)*

The following applies to all donor products (*e.g.*, marrow, PBSC, therapeutic cells, whole blood, etc.) excluding cord blood units (see Section II, below, for relevant terms related to cord blood units.) Entire donor products that are not infused may be cryopreserved, discarded or may be used for anonymous research provided that:

- The NMDP Search Coordinating Unit (SCU) is notified in writing within two business days in instances where a donor product has been collected and the scheduled donor product infusion is cancelled or postponed prior to infusion.
- The NMDP SCU is notified in writing within two business days when an entire donor product will be cryopreserved. A cryopreserved product, or a portion thereof, may be subsequently infused into the intended recipient.
- The NMDP SCU is informed in writing within two business days when an entire donor product that was cryopreserved is infused or discarded.
- The NMDP SCU is notified in writing in advance of an entire donor product that was not infused being used in anonymous research. In these instances:
  a. The NMDP SCU will notify the donor center and the donor center must obtain permission from the donor before the transplant center can use the product for anonymous research;
  b. The product must have absolutely no identifying link to the donor, including but not limited to the NMDP donor identification number and collection date;
  c. The transplant center must notify their local IRB of the anonymous research and follow all federal regulations and institutional policies and procedures for use of leftover biological specimens that were initially collected for a purpose other than the intended research;
  d. The local IRB cannot void the requirement for donor permission, which is an NMDP policy requirement; and
  e. The product must be discarded if the donor does not give permission for the product to be used in anonymous research.

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II. *Entire Cord Blood Units*

Entire cord blood units that are not infused may be discarded or used for anonymous research provided that:

- The NMDP Search Coordinating Unit (SCU) is notified in writing within two business days in instances where a scheduled cord blood unit infusion is cancelled prior to infusion but after the cord blood unit has been transferred to the transplant center.
- The NMDP SCU is informed in writing within two business days when an entire cord blood unit is not infused and is subsequently discarded.
- The NMDP SCU is notified in writing in advance of an entire cord blood unit that was not infused being used in anonymous research. In these instances:
  a. The NMDP SCU will contact the cord blood bank to determine if the cord blood banks policies prohibit the use of cord blood units in research. In these cases maternal donors were told that the cord blood units would only be used for transplant;
  b. The cord blood unit must be discarded if the cord blood bank policies prohibit the use of the cord blood unit in research;
  c. Further maternal donor permission is not required if cord blood bank policies allow cord blood units to be used in research;
  d. The cord blood unit must have absolutely no identifying link to the donor, including but not limited to the NMDP cord blood unit identification number, cord blood bank, and collection date; and
  e. The transplant center must notify their local IRB of the anonymous research and follow all federal regulations and institutional policies and procedures for use of cord blood units that were initially collected for a purpose other than the intended research;.

III. *Partial Unused Products and Unused Donor Specimens*

Leftover specimens and partial products may be cryopreserved, discarded or used for anonymous research. In these circumstances:

- The NMDP does not need to be informed when leftover specimens and partial products are cryopreserved.
- The NMDP does not need to be informed when leftover specimens or partial products are discarded or used in anonymous research.
- Where leftover specimens or partial products are used in anonymous research:
  a. The leftover specimen or partial product must have absolutely no identifying link to the donor, including but not limited to the NMDP donor identification number or NMDP cord blood unit identification number and collection date;
  b. The transplant center must notify their local IRB of the anonymous research and follow all federal regulations and institutional policies and procedures for use of leftover biological specimens that were initially collected for a purpose other than the intended research; and
  c. Donor permission is not required for the use of leftover specimens or partial products in anonymous research.

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STANDARD OPERATING PROCEDURE

OBJECTIVE

Describe the process for requesting and monitoring cryopreservation requests for marrow, PBSC, and T cell collections. Includes process for requesting cryopreserved products for anonymous research.

MATERIALS

1. Personal computer
2. Writing materials

APPLICABLE REFERENCE DOCUMENTS

1. Form #: F00354, Transplant Center Request for Cryopreservation
2. Cryopreservation Approval Letter (Located on SCU reference page)
3. Attachment # A00353, NMDP *Policy for Disposition of Donor Products, Cord Blood Units, and Specimens*
4. Form # F00646, Transplant Center Request to Use Cryopreserved Product for Anonymous Research
5. SOP #: S00269, Management of Post Collection Donor Recovery and IDMs

DEFINITIONS

1. **Cryopreservation:** Preservation of biological materials, such as stem cells, at very low temperatures. This enables the product to be used at a later time, as it remains viable after thawing.
2. **Quality Improvement System:** A system used to capture essential information regarding incidents reported to the NMDP, including cryopreservation requests, protocol deviations and other process deficiencies and failures. The database is managed by Regulatory Affairs of the NMDP Quality Systems and Membership Services Department.
3. **Search Quality Assurance Nurse (SQAN)**-Point person in the Search and Transplant Services department who assists in the management of the Quality Improvement System.

SAFETY

Not Applicable

GENERAL PROCEDURE

Cryopreservation Request

1. Receive written notification from transplant center (TC) to delay a planned marrow, PBSC, or Therapeutic Cells, T-cells collection along with the reason for the delay.
   1.1. In rare circumstances, the SC receives notification from the donor center (DC) indicating the donor is interested in donating but unavailable for the requested time frame. If the DC asks for/recommends cryopreservation as an option, proceed to Step #4 after notifying the TC of the DC preference.
2. Notify DC of request to delay planned collection and ask DC to investigate the possibility of a delay with the donor and apheresis center (AC) / collection center (CC).
   2.1. Reschedule collection whenever possible.

3. When DC reports the availability of donor and AC / CC, notify TC about the options for rescheduling.

   3.1. If rescheduling is possible, remove the existing collection, prep, collection, and transplant dates from SEARCH Link®. Continue with routine procedures for scheduling a new collection date.

   3.2. If rescheduling is not possible, TC may consider cryopreservation of the donor's stem cells.

4. The TC must initiate a cryopreservation request with a letter of medical necessity from a physician or designee at the TC. The letter should include:

   - Current patient status
   - Reason for delay
   - Likelihood of product infusion
   - Planned date for initiation of patient prep and transplant

5. Review letter of medical necessity to ensure receipt of information.

6. Inform DC that a request has been received from the TC and is being reviewed by a manager or NMDP physician.

7. Complete Form #: F00354, *Transplant Center Request for Cryopreservation*

   7.1. Include recipient & donor circumstances leading to cryopreservation request.

8. Forward both the *Transplant Center Request for Cryopreservation* form and letter of medical necessity to a manager or NMDP physician for review.

9. The manager or physician reviews the information and decides to either approve or deny the request. The reviewer documents the decision, the reasoning (e.g. patient condition, donor schedule) and signs the *Transplant Center Request for Cryopreservation* form.

10. If cryopreservation of product is approved, reviewing manager or physician signs form and returns to the SC with the letter of medical necessity.

11. Give a copy of the final *Transplant Center Request for Cryopreservation* to Search Quality Assurance Nurse (SQAN).

12. Fax a cryopreservation approval letter to the TC.

    12.1. Maintain the approval letter, *Transplant Center Request for Cryopreservation* form and the letter of medical necessity in patient chart.

13. Inform DC of cryopreservation approval.

    13.1. Confirm donor agrees with cryopreservation, collection and infusion plans.

        13.1.1. If the donor declines to have product cryopreserved, notify the TC and discuss the other search options.

14. After collection occurs, the SC II/III manages the donor recovery until the cells are infused.

    14.1. Refer to SOP #: S00269, Management of Post Collection Donor Recovery and IDMs.

15. TC provides regular updates on patient's clinical status until product is infused.

    15.1. Contact TC to obtain patient updates as necessary.

16. On planned transplant date, verify with TC that product is infused.

    16.1. Notify DC when the product is infused.

    16.2. If TC confirms product is <u>not infused</u> on planned transplant date, request documentation of new prep and transplant dates from the TC as soon as available.

        16.2.1. When new dates are known, update prep and transplant dates in SEARCH Link®.

17. Repeat Step 16 until product is infused or TC indicates no plans for infusion.

    17.1. When TC indicates the product will not be infused or the patient has died, notify the DC of this outcome.

17.2. Remove prep and transplant dates and add "No plan for infusion" or "Patient Died" in the tentative collection date field in Search Link®.

18. If the TC informs the SC of a product cryopreserved without pre-approval, request documentation of new prep and transplant dates from the TC as soon as available.

18.1. Complete the *Transplant Center Request for Cryopreservation* form and check "unplanned cryo".

18.1.1. Send copy of form to SQAN.

18.1.1.1. Maintain a copy in patient chart.

18.2. Inform DC of unplanned cryopreservation.

19. Perform chart review and give to the SC I to finalize all search stages.

20. Repeat Step 16 until product is infused or TC indicates no plans for infusion

21. If cryopreservation of the product is declined, reviewing manager or physician informed the TC in writing.

21.1. Discuss other search options with TC

21.2. Maintain the form, letter of medical necessity, and written notification to the TC in patient chart.

Product Disposition and/or Anonymous Research

22. When the SC receives written notification from the TC that the product was discarded:

22.1. Notify the DC (courtesy copy the SQAN) of the disposition.

22.2. Place documentation in patient chart.

23. The SQAN or designee enters data into cryopreservation log.

24. When the TC requests advanced approval to use the product for anonymous research, provide them with a F00646, *Transplant Center Request to Use Cryopreserved Product for Anonymous Research* form to complete.

24.1. Receive and review the form for completion.

24.2. Send the form to the DC for review and documentation of donor permission.

24.3. Receive the form from the DC with the donors' response.

24.4. Send completed form to the TC.

24.4.1. If donor declines, refer TC to NMDP's *Policy for Disposition of Donor Products, Cord Blood Units, and Specimens*.

24.5. Send copy of form to SQAN.

24.6. Maintain copy of form in patient chart.

25. SQAN or designee enters the disposition data into cryopreservation log.

Revision History

Revision	Brief Description of Revision
S00219 revision 1.0	New SOP
S00219 revision 2.0	Changed name of SOP and updated to include NMDP Disposition Policy and new process when a TC requests cryopreserved products for anonymous research
S00219 revision 3	Made changes to steps 5,6 and 9. Changed order of SOP to put most common step first (approval of cryopreservation and then decline of cryopreservation).

ADDENDA

Not Applicable