

Marrow Collection Procedures Video Transcript

View the Marrow Collection Procedures Video online: Network.BeTheMatchClinical.org/MarrowCollection

Hello, my name is Shernan Holtan and I am assistant professor of medicine at the University of Minnesota. The University of Minnesota is one of the bone marrow collection centers in the National Marrow Donor Program/Be The Match Network. Many of the transplants facilitated by the NMDP/Be The Match use bone marrow collected from volunteer donors on the Be The Match Registry. These volunteer unrelated donors give their time, energy and life-saving marrow to help patients in need. And dedicated clinicians, like you and me, are instrumental in this process.

This video is designed to provide useful information about the standard marrow collection methods. While there may be alternative collection techniques, the techniques and procedures presented in this video reflect approaches used by many collection facilities across the United States and align with the standards set by the NMDP/Be The Match.

The highest priority during a collection is the safety of the donor. The NMDP/Be The Match supports procedures that meet the needs of the recipient while maintaining donor safety. This informational video should enhance, but not replace, the one-on-one training that is essential for safe marrow collection. Thank you for taking the time to view this program and for your role in life-saving transplants.

Chapter 1: Planning for the Procedure

Planning for the procedure is critical for a successful outcome.

Prior to the day of collection, your center will receive several documents from the donor center. The collection center is responsible for completing the Verification of Hematopoietic Progenitor Cells (HPC) Marrow Request form. The collection center will also receive the Declaration of Donor's Eligibility form and the Infectious Disease Markers Source document.

These documents are essential components of product labeling and need to be included with the product for transport. There may be other forms and paperwork required at your institution.

Careful review and completion of the Verification of HPC Marrow Request form is critical to ensure donor safety and agreement on the Total Nucleated Cells, or TNC, to be collected.

The donor center will have completed Section One of the form.

The collection center must review the information in Section One, which includes:

- Total nucleated cells or TNC requested,
- The maximum volume of marrow and TNC obtainable,
- · Day of collection samples,
- Transport conditions,
- Additional anticoagulant, and
- Any unique transplant center requirements.

If there are concerns about the amount of TNC requested, the collection center should contact the donor center to discuss options.

Once the collection center has reviewed Section One, they will complete Section Two, including:

- Recording the estimated TNC that will be collected,
- Indicating the number of autologous units that will be collected, and
- · Noting additional anticoagulant, media or additives.

It is important to note that NMDP/Be The Match does not require the collection of autologous units and that collection is at the discretion of the collection center.

By signing Section Two, the collection center agrees to accept the collection specifications.

Once completed, the collection center returns the verification form to the donor center for final review and verification by the transplant center.

Just prior to collection, ensure the collecting physician has reviewed the following completed forms:

- Declaration of Eligibility Adult Donor
- Repeat Donor Infectious Disease Markers, or form 50
- Physical Examination form
- Other required forms such as laboratory, EKG and imaging results

On the day of collection, you or your laboratory will need to complete several forms required by NMDP/Be The Match in addition to forms and documents required at your institution.

You will complete the Donor Assessment on Day of Marrow Collection Procedure form (732) at the time of donor evaluation during the pre-op process. This is a physical assessment form including lab results of the CBC and differential.

Prior to the start of the harvest and the donor receiving IV fluids, you must collect blood sample(s) for:

- NMDP/Be The Match required donor samples and testing
- Transplant center requested samples and testing
- Required tube for ABO Rh testing which much be sent with the product

Sign and date pre-op orders according to your institution's standard operating procedures.

Chapter 2: Procedure Set-up and Identifying Landmarks

The two collections in this video were filmed at Lombardi Comprehensive Cancer Center, MedStar Georgetown University Hospital.

The collection procedure is performed in a standard operating room using sterile technique.

The team typically consists of six members:

- Anesthesiologist
- Scrub nurse for sterile activities
- Circulating nurse for non-sterile activities
- Two collecting Physicians, or a Physician and an Advanced Practice Professional who will be performing the aspirations
- A technician for handling bags, marrow, anticoagulant, and preparing the product for transport

It is important to have all documentation and equipment prepared prior to the beginning of the collection. Review with your anesthesia staff the estimated volume to be collected.

Collectors will need disposable harvest needles with stylets specifically designed for marrow collection and 8- 10, 30 milliliters, Luer-lok syringes. Have extra syringes, harvest needles and a pair of sterile pliers on hand.

If it's your center's practice to make an incision for the needle, you'll need one #11 blade with handle. Verify that all instruments are on hand and sterile prior to the start of the procedure. Consider creating a physician preference card that outlines the required supplies for this procedure. For marrow collection and handling you need a collection kit like the BioAccess or Fenwal. A second collection kit should be available in the operating room for back-up. Record the lot number and expiration of the collection kit.

Have the prepared "end of collection" product label, if applicable, and verify all label information.

Review the verification of HPC marrow request form to verify transplant center requirements.

You will also need the anticoagulant, heparin. The transplant center may request other anticoagulants, such as Acid Citrate Dextrose Solution, sometimes called ACD-A, or other additives. You will need a crystalloid diluent such as plasmalyte –formula A or normosol to mix with the heparin and any other required collection anticoagulant. This combination of the crystalloid and anticoagulant will be known as the media. Refer to the verification form for transplant center requests.

Record the lot numbers and expiration dates of the crystalloid and the anticoagulants. Remember to label your media. Add the crystalloid solution containing sufficient anticoagulant to the collection bag, either before or after the harvest per your center procedures.

In this example, the media is mixed before the start of the collection.

Rinse the syringes and the harvest needles prior to the start of the collection with anticoagulant-containing crystalloid solution.

You will need to filter the marrow during or at the end of the collection using sterile filters from the collection kit, made of materials that do not deplete leukocytes.

For donor positioning you will need a variety of pillows, gel pads, a hard hip roll and a support board, such as the Wilson Frame, depending upon the size of the donor and your institution's guidelines.

Identifying Landmarks

The iliac crest has a large amount of red bone marrow, making it the ideal site of bone marrow harvests.

The posterior superior iliac spine is the most common collection area because of its prominence, easy access, and thicker bone wall.

Donor body weight will affect how easy it will be to determine the landmarks. Here you will see the difference between two different donors.

Before the procedure, you will locate and mark the posterior superior iliac crest.

Palpate the posterior superior iliac spine and the prominence of the posterior iliac crest. Mark the locations by drawing an outline using a surgical marking pen.

Outline the lateral edge of the lumbar sacral spine as well.

Although this landmark identification procedure is generally effective, consult your hospital's standard

Chapter 3: Closed System Collection Procedure

In this section, we will review the steps involved in a closed system collection procedure such as the BioAccess Kit.

Before the collection procedure begins, a "time out" must be conducted. It must involve the entire operative team, use active communication, and be documented, such as in a checklist. This information includes:

- Correct donor identity
- Correct site
- Agreement on the procedure to be done
- Review of allergies
- Presence of sequential compression devices for venous thromboembolism prophylaxis
- Verify volume of marrow to be aspirated and when a mid-count will be performed
- Ensure anticoagulants have been added to the collection bag

Remember: donor safety is the first priority. Avoid anything that compromises donor safety or interrupts or interferes with the collection.

The procedure begins with anesthetizing the donor. We define anesthesia "start: time as intubation and "stop" time when the donor is extubated. The anesthesiologist needs to record both times. The maximum anesthesia time is 2.5 hours.

Once anesthetized, transfer the donor from the gurney to a prone position on the table. The donor should be correctly positioned with the pelvis elevated and appropriate padding on all pressure points. Secure the donor to the procedure table using safety straps, and place sequential compression devices on the legs.

Take care to protect the rotator cuff while positioning the arms, then secure the arms to the support boards with foam tape.

Finally, to avoid unnecessary pressure, verify that the donor's breasts or genitals are not awkwardly positioned. Place a blanket over the legs and secure the safety strap.

Next, confirm the landmarks.

Prepare the collection area according to your sterile standard operating procedures, using products that were verified as non-allergenic to the donor. Establish your sterile field with appropriate towels and drapes.

When ready to proceed, the two collectors should stand on opposite sides of the operating table.

Both collectors should palpate the posterior superior iliac spine and the prominence of the posterior iliac crest.

Begin by either making a stab incision of less than 1 centimeter in depth over the posterior superior iliac spine using a #11 blade, or by inserting the harvest needle with the stylet through the skin by applying downward pressure with a twisting motion.

The needle is introduced through the skin, cortex of the bone, and finally into the marrow cavity. You will be able to tell when the needle enters the marrow cavity as the needle advances more easily. The needle should feel firmly anchored or seated in the pelvis. If it is unstable, remove the needle with stylet and reinsert.

Remove the stylet and securely attach a syringe.

To collect the highest concentration of marrow cells relative to peripheral blood, use short, vigorous aspirations of about 5-10 milliliters at a time, rotating the needle 90 degrees after each until you've gone in a full circle to collect about 20 milliliters.

Aspirating only 5-10 milliliters at a time helps avoid pulling excessive peripheral blood into the syringe. The time for a full rotation of 360 degrees should be only a few seconds to avoid marrow clotting in the syringe.

After a full circle of aspirations is completed, remove the syringe from the needle and hand-off the syringe to the team member working the collection bag.

This team member should be situated between the collection team and the collection bag to efficiently empty the syringes into the collection bag.

To avoid damaging the fragile cells, the team member should gently push the marrow from the syringe into the closed collection bag system that contains a mixture of anticoagulants, heparin and diluents. After use, rinse the syringes with heparin per your center's procedures. After every three or four syringes, the team member working the collection bag should gently massage the bag to promote mixing of the marrow and the diluents.

Reinsert the stylet into the needle and advance a few millimeters deeper into the bone.

Repeat the four quadrant aspiration process. Continue this repeated process until reaching the opposite cortex, taking great care not to advance the needle too far into the bone. This will be signaled by the increased force necessary to advance the needle.

To reduce dilution of the marrow with blood and collect a higher number of total nucleated cells, advance no more than three times, aspirating no more than about 10- 20 milliliters per advancement.

To continue the aspiration procedure, withdraw the needle from the initial insertion site, move a few millimeters from the last insertion site to a new area of solid bone on the crest and repeat the aspiration process.

From the first skin incision, it should be possible to cover a fair area of the iliac crest. Because this skin moves readily over the crest, multiple skin incisions are not needed.

If a new incision is required, it should be placed 1-3 centimeters from the original site superiorly and laterally along the iliac crest.

Throughout the procedure, the physician informs the anesthesiologist how much marrow has been collected per institution standard operating procedures. The anesthesiologist monitors the status of the donor's vital signs and provides intravenous fluid replacement as needed.

Continue aspirations until about one half of the estimated volume has been collected. Volume is determined by the prescription and the total volume calculation determined prior to the start of the procedure.

At the mid-point in the collection the scrub nurse notifies the technician, or circulating nurse, to switch bags.

Cap the first bag and start collecting in to the second bag.

While the collection continues, the first bag's cells should be tested to determine the current cell counts and how much additional marrow needs to be collected. This is very important to make sure that the proper amount is collected and to keep the donor safe.

There are several ways to facilitate testing the cell count. The recommended approach is to send a 1-1.5 milliliter sample of filtered cells to the lab for a STAT cell count. When possible, request that lab personnel pick up the specimen from the OR to speed up getting the cell count results from the lab.

The collector verifies the original cell dose calculations against the mid collection cell count to determine how much more marrow to collect.

The collection proceeds until the final cell dose is reached, the maximum volume has been reached, or the maximum anesthesia time limit of 2.5 hours is reached.

Remember to record the end point of anesthesia at extubation as required for CIBMTR data forms.

Calculate the total blood loss, which is equal to the total collection volume minus the anticoagulant solutions.

After the collection is complete, clean the incision sites with saline or sterile water. Marcaine or bupivacaine 0.25% without epinephrine may be applied to the skin around the incision area and the periosteum for pain control. Apply benzoin and steri-strips to the incision sites and bandage as necessary.

Turn the donor from prone to supine, and transfer the donor from the OR bed to the gurney.

The anesthesiologist gives the donor agents to reverse anesthesia and performs extubation. The anesthesiologist will make the decision when it is medically appropriate to transfer the donor to the recovery room. The donor's vital signs are monitored until he or she is stable.

The collecting physician or coordinator then informs the donor's family that the procedure is complete. Include an update of the donor's condition and a reminder of the amazing gift they are giving.

Chapter 4: Product Handling

Upon completion of the procedure, filter marrow from the collection bag(s), collect required product samples for testing, and remove all air from the transfer bags. The marrow must be divided into approximately equal portions and placed into at least two sterile, closed bags, each with ports which can be entered aseptically. Ideally the marrow bag tubing should be sealed using a heat sealer, leaving as long of a tail as possible to allow for sterile docking, if necessary.

Complete and affix the end of collection labels in the OR. Be sure to maintain confidentiality.

It is advisable to complete the Marrow Product Analysis form (form 772) immediately after the collection. Record the volume of marrow collected and the amount of anticoagulants, heparin, diluents, or any other additives added to the marrow.

Also complete form 732 titled Donor Assessment on Day of Marrow Collection Procedure. Remember to include the start and end time of anesthesia.

Place marrow in a validated rigid container for transport.

Marrow must be transported at the temperature requested by the transplant center on the verification form.

Immediately take the labeled marrow, Donor Assessment on Day of Marrow Collection Procedure form (732), and the Marrow Product Analysis form (772) to the lab for processing.

The collection center must not add anything, process, or cryopreserve product except as requested by the transplant center and approved by NMDP/Be The Match.

The final product volume must be determined by the net weight of the product, where 1.06 grams equals 1 milliliter of product. Take the final weight minus the weight of the empty bag divided by 1.06 to calculate the final volume of the product.

Final product labeling must follow NMDP/Be The Match requirements.

Marrow must be hand-carried by trained courier. Prompt processing and pickup is essential in the delivery of the marrow to the waiting transplant recipient. Communicate any changes in scheduling, or pick up location to the courier as soon as possible.

Chapter 5: Post-op Donor Care

Post-op care of the donor prior to discharge will depend upon the institution's policies and procedures. It is important for the volunteer marrow donor to feel their contribution is genuinely appreciated. A marrow collection team member should accompany the donor to the recovery room, and then stay in contact with the recovery room staff.

When the donor is fully awake, the collection team member should check in with the donor to verify how he or she is feeling.

At this point, a blood sample should be obtained for a complete blood count (CBC) and differential. Prior to discharge from the collection center, check the collection site to verify the donor is not bleeding. Change or reinforce the dressing as necessary.

Provide the donor and/or care giver with discharge instructions including all required NMDP/Be The Match post-donation information, contact information, precautions, and directions for management of pain or nausea.

Remind them if there are problems or questions, they need to call the contact listed on the discharge instructions.

The donor is usually discharged the same day if:

- 1. They are ambulating with normal vital signs and have voided
- 2. They are able to tolerate oral fluids
- 3. Their discomfort and pain are under good control with oral medications
- 4. They have a companion

Call the donor within 24-hours to ensure there are no complications or questions.

This completes the collection procedure. Thank you for taking the time to view this program and for your role in life-saving transplants.