

Title:

**Section 11.0 NZBMDR STANDARDS  
GUIDELINES FOR the COLLECTION of  
BONE MARROW**

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## Forms

Donor Stem Cell Collection Checklist	Form 42
Transplant checklist	Form TX 01
Final Compatibility Test Results	117
Formal request for Stem Cell Collection	MC001
Prescription for Bone Marrow Collection	MC002
Verification of Bone Marrow Prescription	MC003
Interpretation of Third Party Physical Exam at Workup	Form 43
Donor Infectious Disease Markers at Workup	Form 50
Intent to Donate Bone Marrow	Form B
Bone Marrow Collection Report	Form 60
Donor Hospitalisation Record	Form 61
Work up request Acknowledgement	Form WU01
NZ Donor Final Clearance	Form WU 02

## SECTION 11.0 NZBMDR STANDARDS GUIDELINES FOR COLLECTION OF BONE MARROW

### INTRODUCTION

Collection of stem cells from an NZBMDR donor will be approved under criteria listed in the publication “ Indications for Haematopoietic Stem Cell Transplantation” compiled by the Bone Marrow Transplant Study Group of the Haematology Society of Australia and New Zealand.

If a Transplant is considered Non-standard, High Risk or Experimental under these criteria the Scientific Advisory Committee will make a decision as to whether the collection will be approved. If the collection is approved the donor must be informed of the committees reasoning before deciding whether to proceed with donating stem cells.

NZBMDR will release donors to Transplant Centres searched by Donor Centres participating on BMDW. Other Transplant Centres are required to forward credentials before a donor will be released.

NZBMDR allows a one antigen mismatch between patient and donor.

### 11.1 FORMS REQUIRED TO REQUEST A DONOR WORKUP

To request 'Work Up' on a donor for collection of bone marrow the following forms or their international equivalent must be completed

**Form 117 (Final Compatibility Test Results),**

**Form MC001 ( Formal Request for Stem Cell Collection)**

**Form MC002 (Prescription for Marrow Collection)**

All actions will be recorded on **Form 42 Donor Stem Cell Collection Checklist**

For NZ patients all actions will be recorded on **Form TX 01 Transplant checklist**

**Form WU01 Work up request Acknowledgement** to be sent to the Transplant centre acknowledging the request and giving workup dates

### 11.2 PRE-DONATION EVALUATION OF BONE MARROW DONORS

The third party donor information session and medical assessment must be conducted by a haematologist who is not part of the team treating the patient. The donor must be given the opportunity to have an advocate or third party (e.g. family member or friend) present at the pre donation evaluation session.

#### 11.2.1 Donor Information and counseling

The purpose of this session is to provide information regarding the Marrow/PBSC collection procedure, clearly outlining the potential risks to the donor including the risk of an anaesthetic.

Topics to be covered by the Donor Centre Coordinator or authorised representative and the third party haematologist include

- **Tissue Typing** - Brief description showing why this donor has been chosen
- **Patient Details** - Age group, Sex, Continent, Racial Background (if appropriate)
- **Transplant from the Patient point of view**
  - Disease transplanted for
  - Conditioning and work-up for patient (10 days)
  - Point of no return
  - Post transplant complications including GVHD including possibility of death
  - Success rate of unrelated transplantation
  - If the Transplant is an experimental procedure, or clinical trial (if known) the donor should be made aware of this situation
  - First signs of Engraftment (21 days)
- **Procedure for Donor**
  - Blood samples for Infectious Disease markers and other blood tests
  - Pregnancy test (if appropriate)
  - Collection process
  - Place of collection
  - Autologous unit if required
  - Risk of donation
  - Time off work and other activities such as sport
  - Patient progress reports if wanted (at 1 month, 3 months, 6 months, 1 year, yearly)
  - Possibility of a second collection
  - Possibility of the transplant not being successful
  - Samples for research – if requested and approved by scientific committee
  - Cover for expenses and lost wages
  - Insurance
  - Patient/Donor Confidentiality

### 11.2.2 Medical Clearance

A full medical history will be taken and the donor will require a range of tests to be performed to ensure that he/she is a satisfactory candidate for bone marrow/PBSC donation and the loss of up to 1500 mls of marrow/blood if a marrow collection is performed. These tests include a full blood count, blood grouping, urea, electrolytes, liver function tests, chest Xray, ECG and antibody testing for CMV, HIV, HbsAg, STS, HCV, and HTLV1.

**NZBS Blood Donor Session Record Form** must be completed to the satisfaction of the Donor Centre.

Infectious Disease marker testing must be performed within 30 days of the Collection date. The results of Infectious Disease tests performed at Workup should be reported within five (7) days of testing.

Positive results for any of these infectious disease markers will not necessarily exclude a person from donating marrow. The Transplant Centre, the Collection Centre and the Executive Officer of NZBMDR must be made aware of any positive results so a decision can be made as to whether to proceed with the transplant.

Virology testing by NAT (Nucleic Acid Testing) should be performed by the NZBS at workup. Virology results must be recorded on **Form 50 (Donor Infectious Disease Markers at Workup)**.

**Form 43 (Interpretation of Third Party Physical Exam at Workup)**, must also be completed at this stage.

**Form B (Intent to Donate Bone Marrow)**, must be signed by the donor prior to release of donor clearance. If the Transplant is an experimental procedure, or clinical trial (if known) the donor should be informed of this situation before signing Form B

**Form MC003 (Verification of Marrow Prescription)** must be completed at the time of the donor information session.

When donor clearance has been completed **Form WU02 NZ Donor Final Clearance** will be sent to the Transplant centre confirming donor clearance and seeking Transplant Centre acceptance of the donor.

A letter should be sent to the donor's general practitioner with the donor's medical results and intention to donate stem cells.

### 11.2.3 Precollection samples

If pre-collection samples are required, no more than 50 ml of peripheral blood should be requested. Transplant Centres requiring more than this amount must submit a request to NZBMDR with a formal research proposal.

### 11.2.4 Testing following Transplant Postponement

In the event of postponement of the transplant it may not be necessary to repeat the third party haematological assessment. However this will be a decision made by the Collection Centre Director on a case by case basis. Virology testing must be repeated within thirty days of marrow collection.

### 11.2.5 Pregnancy testing

All women of childbearing age must be asked if there is a likelihood of pregnancy and offered a pregnancy test. If they decline to have the test this must be documented on Form 43 (Interpretation of Third Party Physical Exam at Work-up). If there is a possibility of pregnancy, the woman should have a pregnancy test. A full disclosure of risk must be given to the woman with regard to the possibility of foetal malformation and/or miscarriage if the donation proceeds and she is pregnant.

Chest X-Rays for female donors, with a possibility of pregnancy, should be avoided.

## 11.2.6 Autologous Red Cell Units Collected Prior to a Bone Marrow Harvest

The collection of a unit of autologous red cells from the donor will be decided by the third party Haematologist at workup. Unless the donor weight is very small in comparison with the patient weight an autologous collection is not recommended.

**refer: Preoperative autologous blood donation for bone marrow harvests: Are we wasting donor's time and blood? A.Mijovic et al Transfusion Medicine, 2006 16, 57-62)**

## 11.2.7 Counselling Donors Identified with Abnormal test Results

All donors identified as having abnormal test results must be contacted by the professional body identified in SOP 806.

Follow up tests or treatment should be arranged by this body in consultation with the donor.

NZBMDR must be informed with appropriate details and information about temporary or permanent unavailability of the donor. This information is to be recorded in the donors file. The Transplant Centre must be informed in writing if issues of donor health pertain to the safety of the patient or to the removal of the donor from the Registry

## 11.3 ALLOGENEIC RED CELL UNITS

Allogeneic transfusions are discouraged but if the need arises the blood must be irradiated with at least 25Gy (2500 rads).

## 11.4 COLLECTION of BONE MARROW

The NZBMDR expects that all participating Transplant Centres with the exception of STARSHIP will also act as Collection Centres for transplants which take place in NZ or overseas. Attempts should be made to collect the marrow in a hospital other than the one in which the recipient is being treated. The National Office will collaborate with the Transplant Centre to choose a satisfactory collection facility. If difficulties arise in deciding the site for marrow collection, the Executive Officer will make the final determination

- Marrow will be obtained only from the posterior iliac crests.
- Only in exceptional cases should spinal anaesthesia be used.
- The volume of marrow aspirated at each site should be kept to a minimum (usually 5-10 ml) to reduce the dilution of marrow with peripheral blood.
- The amount of marrow to be aspirated will be influenced by the following factors:
  - i the weight of the donor; **The total volume of marrow aspirated should not exceed 20 ml/kg donor weight.**
  - ii the donor's and recipient's ABO blood types;
  - iii any requested manipulation of the marrow.

- To ensure that an appropriate number of nucleated cells are collected cell counts should be taken half way through the collection procedure. The total number of nucleated cells collected must be tabulated and reported on Form 60, Bone Marrow Collection Record. In general, at least 10-20 ml of marrow should be aspirated for every kilogram of recipient weight with a target of  $3 \times 10^8$  nucleated marrow cells/kg recipient weight.
- Once aspirated, the marrow should be collected into an anticoagulant solution according to procedures validated at the collection centre. If ACD is the sole anticoagulant, marrow may be collected directly into this solution. For donations for patients within New Zealand or Australia, heparin alone may be used (assuming 8 hours or less marrow transport time). Donations to overseas patients generally require longer than 8 hours marrow transport time and the preferred anticoagulant is ACD 1:5 (heparinised syringes are used for aspiration).
- **HEPARIN MUST NOT BE INJECTED INTO THE BAGS OF MARROW DURING THE TRANSPORT OF THE MARROW**

### 11.5 LABELLING

Containers must be clearly identified using labels that remain intact under the storage conditions used.

The label on the unit must have the name of the product, the product ID, the volume of product, the NZBMDR donor ID, the recipient's name, the recipient's ID, date of collection, the volume and type of anticoagulant and the ABO and Rh (D) group.

### 11.6 COLLECTION OF BLOOD SAMPLES AT THE TIME OF MARROW COLLECTION

Blood samples from the donor should be collected for the Transplant Centre as requested on the Bone Marrow Prescription Form for :

- (a) white blood cell count and red cell phenotype (EDTA, 5 ml) and
- (b) blood type and antibody screen (clotted tube, 10 ml). These samples must be taken at the time of marrow collection, labelled and transported with the marrow to the Transplant Centre

### 11.7 STORAGE LIMIT

Every effort should be made to transfuse bone marrow within 8 hours of collection for New Zealand recipients and within 30 hours of collection for recipients outside New Zealand. This may not always be possible for international patients.

### 11.8 PROCESSING THE BONE MARROW

Marrow may be processed at the Transplant Centre for volume reduction, ABO incompatibility and prevention of GVHD. Bone marrow should not be cryopreserved (refer: Section 19.0).

## 11.9 CULTURES

To confirm lack of microbial contamination marrow should be placed into culture for bacteria and fungi at the Transplant Centre, employing aerobic and anaerobic conditions. It is recommended that cultures be performed also at the Marrow Collection Centre, with timely reports to the Transplant Centre.

## 11.10 VIABILITY

Viability count should be performed on each bag of marrow (if more than one) or the final marrow pool, on arrival at the Transplant Centre.

## 11.11 NUCLEATED MARROW AND BLOOD CELL COUNTS

These should be performed on arrival at the Transplant Centre.

## 11.12 BLOOD GROUPING OF MARROW

This must be performed on arrival at the Transplant Centre and the result recorded in the Transplant Centre's Blood Centre and the transplant physician at the Transplant Centre informed.

## 11.13 BONE MARROW COLLECTION REPORT

**Form 60, Bone Marrow Collection Report**, must be completed to accompany the marrow. This form gives details of the product and peripheral blood samples collected

## 11.14 DONOR HOSPITALIZATION RECORD

**Form 61, Donor Hospitalisation Record** must be completed giving information regarding the marrow collection procedure and the donor experience in hospital.