Title:	**Section 11.0 NZBMDR STANDARDS GUIDELINES FOR the COLLECTION of BONE MARROW**
Authorised by:	Executive Officer

Contributing Authors:
Scientific Expert Advisory Committee (ABMDR)

Raewyn Fisher

Dr Hilary Blacklock

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SECTION 11.0 NZBMDR STANDARDS GUIDELINES FOR COLLECTION OF BONE MARROW

INTRODUCTION

Collection of stem cells from an NZBMDR donor will be approved under disease indications approved by the Ministry of Health Guidelines of 2011 and updated in 2018 Theses are based on These are based on the ASBMT / ASTCT and EBMT indications for transplant.

If a Transplant is considered Non-standard, High Risk or Experimental under these criteria the BMT Special Interest group 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. (WMDA Quality and regulation working group form **WMDA Transplant Center Evaluation Form** to be used to evaluate unaccredited Transplant centres)

NZBMDR allows a one antigen mismatch at A*, B*, DRB1* between patient and donor.

11.1 FORMS REQUIRED TO REQUEST A DONOR WORKUP

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

Tissue typing report with high resolution VT results from Patient and Donor
Form HPC Prescription (Request for Stem Cell Collection)

For overseas patients 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**

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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

Before any testing commences the identification of the Donor must be confirmed by a legal document such as a passport, birth certificate or Drivers license

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 in to provide information regarding the Marrow/PBSC collection procedure, clearly outlining the potential risks to the donor including the risks 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.

- **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 and 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
  Collection process
  Place of collection
  Autologous unit if required
  Risks associated with donation
  Time off work and other activities such as sport
  Patient progress reports if wanted (at 2 months, 6 months, and then yearly for 10 years)
  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
  Release of details to donor's GP

11.2.2 Medical Clearance

A full medical history will be taken and a range of tests will 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 (ABO Blood group and Rh factor), urea, electrolytes, liver function tests, chest X-ray , ECG and antibody testing for CMV, HIV, HbsAg. STS. HCV, and HTLV1, EBV and Toxoplasmosis.

Following Guidelines set by the Anthony Nolan and NMDP registry and discussion with other registries **NZBMDR recommend that the donation of marrow be restricted to donors with a BMI of 35 or under** and PBSC to those with a BMI of 40 or under. However a donor with a higher BMI may be cleared for donation if the third party

Haematologist recommends this, taking into account the donors build. White blood cell count on day 5 must be taken prior to the donor receiving a final GCSF injection.
Donor safety must be the guiding factor in decisions to extend this level of BMI when deciding on the eligibility of a donor

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 prior to Collection date. The results of Infectious Disease tests performed at Workup should be reported within seven (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. The final decision will be made by the TC 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
GC002 (Verification of HPC collection) 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.

If the donor will not be available for a marrow collection even in the unlikely case that the donor is a poor mobiliser **Form WU03 Poor Mobiliser Information** must be forwarded to the transplant centre. This form allows the Transplant centre to

- continue with the agreed schedule
- cryopreserve the cells and postpone the date of transplantation

A letter should be sent to the donor's general practitioner, if the donor agrees, 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 prior to HPC 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 need for a 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 HPC, MARROW

All marrow collections will take place at a NZBMDR accredited hospital.

- **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 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 ideal weight with a target of 3×10^8 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 ACDA 1:5 (heparinised or ACD 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 donor ID, 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 HPC Prescription Form .

(a) These samples must be taken at the time of HPC collection, labelled and transported with the product to the Transplant Centre
(b) For NZ donors blood samples must be sent to Cell Markers who will contact NZBMDR with the cell counts from the final product
(c) The results from cell markers will be entered onto the collection report which will accompany the product

(d) If results from cell markers are not available when the product is collected they must be faxed and/or Emailed to the TC and the requesting HUB as soon as possible

11.7 STORAGE LIMIT

Every effort should be made to transfuse HPC 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 from international donors.

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 unless donor permission has been granted prior to collection (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 .

11.13 BONE MARROW COLLECTION REPORT

Form 60, Bone Marrow Collection Report,

This form must be completed after the stem cell collection by a senior member of the Collection team and should accompany the stem cells to the Transplant Centre. This form gives details of the product and peripheral blood samples collected. If any data is not available to accompany the stem cells it must be faxed or emailed to the collection centre the following day.
The form must also be faxed/emailed to NZBMDR.

11.14 DONOR HOSPITALIZATION RECORD FOLLOWING A MARROW COLLECTION

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

11.15 ADVERSE EVENTS AFFECTING DONORS

If an adverse event

1) occurs during harvest of HPC
2) continues long term as a consequence of the donation
3) Occurs due to registry operations impacting the health and safety of a donor

The Medical Officer will be responsible for defining, identifying, documenting, investigating and overseeing corrective action of the event.
If the donor's health may impact on the patient in any way including subsequent donations the medical officer will notify the transplant centre in writing.
The event must also be reported to SEAR and/or SPEAR