Hematopoietic Stem Cell Registries: WMDA definitions of a Donor Center
(September 2004)

N. Sacchi1, P. Costeas2, L. Hartwell3, C.K. Hurley4, C. Raffoux5, H. Greinix6

1 Italian Bone Marrow Donor Registry, Genoa, Italy; 2The Cyprus Bone Marrow Donor Registry, Nicosia, Cyprus; 3The Anthony Nolan Bone Marrow Trust, London, United Kingdom; 4Department of Oncology, Georgetown University Medical School, Washington, DC USA; 5France Greffe de Moelle, Paris, France; 6 Clinic for Bone marrow Transplantation, Vienna, Austria

on behalf of the Quality Assurance and Clinical Working Groups of the World Marrow Donor Association.

One of the objective of World Marrow Donor Association 1, 2 is to establish internationally acceptable recommendations, standards and procedures in the search for unrelated hematopoietic stem cell donors on behalf of patients in need of transplantation. Two of the WMDA’s working groups, Clinical and Quality Assurance collaborated in the development of this article. This paper presents recommendations and procedures for the recruitment of new volunteer donors. Additional requirements and recommendations can be found in other WMDA publications 3, 4. The present document takes into account also the European Guideline for Bloodbanking. (Europe 2002\98\EC)

The guidelines described here provide recommendations on:

1. What is a Donor Centre
2. Functions and responsibilities
3. The facilities needed to recruit volunteers
4. The expertise and training of personnel involved in donor recruitment
5. The management of the volunteer donor file and the donors’ data

1. WHAT IS A DONOR CENTRE

In many registries the volunteer is usually welcomed and evaluated in an established structure, the Donor Centre (DC), that often is a blood bank or a transfusion centre, but it can be another organisation adapted to suit the operations to be carried out. The recruitment of the volunteers might also be organised at external sites where the medical questionnaires are filled out and the blood samples collected, in some cases with the co-operation of family physicians. Another alternative includes counselling the new volunteers over the phone and inviting them to go to a specific hospital or clinic for the blood drawing. The personnel in charge of contacting and/or counselling the donors should have demonstrated experience in the recruitment and management of potential donors (including education, counselling, confidentiality issues and medical screening) and an adequate knowledge of the responsibilities of a DC. The DC, or the organisation established to carry out its functions, should apply established criteria and principles for informing the volunteers and for donor health screening. The DC should use adequate educational material and consent forms, as established by the registry.

2. FUNCTIONS AND RESPONSIBILITIES OF A DONOR CENTRE
In selecting individuals for stem cell donation, the main goals are to give them the appropriate information about the donation process and to ensure that they are medically eligible. This protects both donor and recipient. The DC has to fulfil these functions at all the stages of the donation process from the initial recruitment to the selection for donation, adapting and modulating these functions in a way pertinent to each stage.

In particular the DC has the responsibility to carry out the following functions:

- **to inform the donor**: due to the complexity and seriousness of the hematopoietic stem cell donation, each step in the recruitment of a potential donor is a graded presentation of information which will solicit a graded commitment from the donor. To assure an informed consent, the volunteer must be given information, educational material and literature pertinent to each of the stages of the donation process;

- **to collect donor personal information**: the DC needs to collect and to store name, date of birth, address and other non-medical information useful to trace the donor in an easy way. The DC is responsible for storing these records at a designated site, and to maintain their authenticity, integrity and confidentiality.

- **to collect donor medical data**: to evaluate the medical eligibility of the volunteer as a stem cell donor, the DC must obtain relevant information about their medical history and general health. Depending on the different stages of the process, this is done through a questionnaire (recruitment) or through physical exams (work up);

- **to collect the blood samples for HLA testing**: the DC is also responsible for co-ordinating the interaction with the donor to facilitate further tests, approaching the donor directly or delegating other established organisations to do so. The DC has the responsibility for co-ordinating the collection of blood samples or other biological material (buccal swabs) used to perform the HLA testing necessary for the recruitment step and in the proceeding stages of the search process;

- **to protect the donor privacy**: one of the fundamental principles of the unrelated stem cell donation is the right of the potential donor to go through the donation process with a minimum of extraneous influences and pressures. To guarantee that, the donor’s identity must be protected. Therefore all the activities related to the donor’s physical examination and collection of personal data must be performed in a dedicated and restricted space, as the access to all the donor information (medical and personal) must be protected and limited to authorised individuals;

- **to transmit the donor’s data to the Registry**: the DC must transmit the donor’s data necessary for the search process to the registry, through an efficient and secure system of communication that maintains the integrity of the data.

- **to ensure that adequate insurance is in place**: Registry should offer disability and death benefits to all stem cell donors. These benefits might be provided through insurance coverage. The DC has the responsibility to verify that a donor insurance to cover the complaints of the donor following blood-draw, evaluation, workup and collection is in place. The DC must notify the volunteer of available insurance cover prior to any procedure. The DC has also the responsibility to verify that the personnel dedicated to the blood collection and donors’evaluation is covered by appropriate general liability and malpractice insurance against donors’ claims for malpractice or accidents related to any service or treatment provided.
If the registration of new volunteers is done by a community clinic, sometimes organized by relatives of a particular patient, there should be a collaborative agreement with an established DC. It must be clearly stated that the clinic must recruit new donors prepared to donate to anyone in need and not specifically for one patient. The recruitment must take place in accordance with the Registry criteria and priorities. In any case the DC is responsible for liaising with the media and overseeing the publicity material to ensure that appropriate information is given to general public.

3. **The Facilities Needed to Recruit Volunteers**

   The recruitment of a new volunteer can occur in a number of places such as a Donor Centre, a Blood Bank or an organised recruitment clinic. Regardless of its location, every “recruitment site” should have adequate resources to support donor recruitment and other related activities and comply with all relevant legislation and regulations of the country and of the Registry. The facilities should have adequate heating, lighting and ventilation, proper sanitation, compliance with fire and safety regulations and sufficient space for the size of the recruitment activity. The facilities should permit the potential donor to answer any medical queries in confidence. During the blood sample collection, the safety and the comfort of the donor and the clinic staff should be assured.

   The donor recruitment site should include the following three areas:

   - a reception area
   - a counselling area
   - a medical area

   The potential donors should be welcomed at the reception area where they can read the donor information material. In that area the donor should have the opportunity to ask basic non-medical questions and fill out the donor application form.

   The premises should include a counselling area where the recruitment officer will explain the full implications of being a donor, will review or assist in the completion of the medical questionnaire and discuss with the donor any medical queries in confidence.

   The medical area is where the blood sample is drawn. The medical area should satisfy common sense requirements for the health and safety of the medical staff and the volunteers. A rest area should be provided for donors who may feel faint or unwell after the blood collection. The rest area should be equipped with a camp-style bed preferably placed behind a screen.

   The recruitment site must have access to an HLA typing laboratory and the procedure for transport of blood samples to the laboratory in a timely fashion must be clearly established.

4. **The Expertise and Training of Personnel in the Donor Centre**

   The recruitment site must have an adequate number of suitably qualified personnel. The tasks and responsibilities of all individuals must be clearly understood and documented. All the personnel involved in the registration and medical evaluation of the volunteers should receive adequate training and educational material. The recruitment site staff are divided into two categories, the administrative staff and the medical staff. The administrative staff will welcome the donors, distribute information packs and help with the completion of the application form. They should have a good knowledge of...
the parameters of being a donor and be able to answer any basic non-medical questions of the applicant.
The medical staff is responsible for the medical counselling of the donor, the review of the medical questionnaire and the collection of the blood samples. The medical staff must include at least a physician who is able to assume the medical responsibilities related to volunteer donor management. This person must also have the capability to consider the medical eligibility criteria for donor recruitment and selection, as defined by the country laws and by the Registry. A medical doctor or other qualified personnel should be available during the recruitment process to cover any medical emergencies that may arise. The blood withdrawal must be performed either by a phlebotomist, a qualified nurse, or a medical doctor. All medical staff should be vaccinated for Hepatitis B and be aware of the policy regarding needlestick injury.
In general the donor recruitment personnel must have a good knowledge of:
- eligibility criteria of a potential stem cell donor;
- conditions leading to permanent deferral (rejection);
- conditions leading to temporary deferral (suspension);
- the role of volunteers donors as a source of stem cells;
- the implication for the donor regarding specialised forms of donation (such as leucopheresis after administration of stimulating factor);
- the laws and rules which protect the anonymity of the donor and the confidentiality of donor data;
- the risk of diseases transmittable by transfusion or transplantation.

The DC personnel must have practical competence in:
- counselling of the volunteers;
- confidentiality issues;
- medical screening.

The DC personnel should also have the capability to:
- discuss the volunteer any further questions or doubts with;
- refer the donor to an appropriate source of medical care in case of unusual complaints;
- review documentation related to donor management (medical history, physical exams).

5. MANAGEMENT OF THE DONOR FILE AND DONORS’ DATA

The DC must keep all written documentation related to donor management (informed consents, medical history, results from physical exams) and it must be available for review by approved Donor Centre staff. The DC should have a designated site for record storage and must maintain the authenticity, integrity and confidentiality of all records. Access must be limited to authorised individuals. The DC must establish procedures to protect the confidentiality of the donor data and to assure the strict anonymity of donors and recipients, taking into consideration national rules and laws on data protection. The DC must store records for the period which meets the legal requirement for that country. Finally, there must be an efficient, secure system of communication between the DC and the Registry so that donor data are directly transmitted without re-entry. If this is not possible, the DC must be able to review and audit the data captured by the Registry.
References


