The Danish Bone Marrow Donor Registry
DBMDR

Vision

To achieve and maintain a position as an internationally recognized hematopoietic stem cell donor registry with respect to high quality of donor data base and HLA typing, individualized, rapid, and reliable services, smooth donor work-up and stem cell donation, and conscientious follow-up.

To achieve and maintain a position of an active participant in national and international collaboration with donor registries and transplant centers.

Through the quickest possible way to identify matched unrelated donors or cord blood units for patients in Denmark waiting allogeneic HSC transplantation with an unrelated donor.

Mission

To maintain a data base of 30,000 – 35,000 or more HLA typed volunteer HSC donors recruited among blood donors in Danish blood banks in North Region of Denmark, Central Region of Denmark and the Region of Southern Denmark and to make these donors available for donation of HSCs and other cell types (e.g. lymphocytes) relevant for allogeneic HSC transplantation

To quickly identify, through national and worldwide donor and cord blood units searches, a matched HSC donor or umbilical cord blood unit for domestic patients awaiting an unrelated allogeneic HSC transplantation

History and current organization

DBMDR was originally established as cooperation between all blood banks in Denmark and the tissue typing laboratories and located at the University Hospital in Aarhus. Later it was decided to establish an
additional registry in Copenhagen, which covered patients and donors in the eastern part of Denmark. DBMDR now recruits volunteer HSC donors in cooperation between the blood banks in the North Region of Denmark, the Central Region of Denmark and the Region of southern Denmark. In addition to running the donor registry, DBMDR has since its start performed unrelated donor searches for Danish patients from the North Region of Denmark, the Central Region of Denmark and the Region of southern Denmark on behalf of the transplantation centers in at the National Hospital in Copenhagen and Aarhus University Hospital.

DBMDR is a regular service unit within the Department of Clinical Immunology at Aarhus University Hospital. Dept. of Clinical Immunology has functions as a regional blood bank and transfusion service, HLA typing laboratory, Apheresis Centre and laboratory for Infectious disease markers.

**Collaboration and certifications**

DBMDR is aiming at complying with standards, recommendations and guidelines of World Marrow Donor Association (WMDA) as well as other international and national regulations.

DBMDR is a member of WMDA. DBMDR regularly submits HLA data of its donors to Bone Marrow Donors Worldwide (BMDW). DBMDR is participating in the EMDIS system (European Matching and Donor Information System). DBMDR is affiliated with the National Marrow Donor Program (NMDP) as a cooperative registry. Furthermore, DBMDR is licensed by the Danish Health Authority as a tissue establishment according to the Danish Tissue Act No. 273 of 01/042006 and regulation No. 984 of 02/08/2007 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells (EU and Commission Directives on human tissue and cells). This licensed tissue establishment also covers functions performed by the Collection Centre (Dept of Clinical Immunology and Dept. of Hematology, Aarhus University Hospital) and testing for Infectious Disease Markers. DBMDR works under the Danish Act of Data Protection and the Act of Public Health.

Department of Clinical Immunology is accredited by the European Federation of Immunogenetics (EFI) for HLA typing and donor-patient transplantation immunology for organ and HSC transplantations.
DBMDR has a formal agreement with the blood banks in North Region of Denmark, the Central Region of Denmark and the Region of southern Denmark and the two Transplantation Centers (National Hospital Copenhagen and Aarhus University Hospital)

ABO and Rhesus typing are performed at the blood banks. They are all approved by the Danish Health Authority according to the Danish Act of Blood. Blood collection, ABO typing and cross-matching for autologous erythrocyte transfusion following a bone marrow donation takes place at the blood bank of Aarhus University Hospital (Dept. of Clinical Immunology).

Recruitment of donors in DBMDR and collaboration with blood banks

A donor can be recruited to DBMDR when the following requirements are met:

- The donor has been accepted as a blood donor and meets the national standards for blood donors according to the EU directive for blood transfusion and national Standards for Transfusion (TMS) in Denmark developed and maintained by the Danish Society of Clinical Immunology.
- The donor is between 18 and 45 years old at time of recruitment (donors up to age 60 can occasionally be accepted)
- A donor has given written informed consent to participate in DBMDR

A donor is removed from the data base when:

- A donor’s health condition is listed in the exclusion criteria of the WMDA Guidelines for donor eligibility
- The donor is older than 60 years
- The donor cannot be traced
- The donor wishes to be removed
- The donor is for other reasons not eligible for donation
Personal data security and informed consent for donors in DBMDR

Donors are requested to provide an informed written consent when joining DBMDR, when blood samples are shipped for Verification Typing and when asked to donate HSC or lymphocytes. All participation in DBMDR is voluntary and the donors are informed that they can withdraw at any time without explanation. Donor’s name, date of birth, social security number, and blood group are revealed by the blood banks to DBMDR. These data are together with the HLA typing data and donor unique identification (ID) number, filed in the DBMDR data system. ID number, HLA types, ABO types, gender and age is the only information in communication with registries around the world.

DBMDR is a regular entity of Aarhus University Hospital. The DBMDR personnel, as well as the personnel at the Collection Center and other collaborating units are working under confidentiality. All personnel have only access to the computer system through a secure log in procedure. In addition only DBMDR personnel have access to the data file and DBMDR data system through an additional secure log in procedure.

Characterization of donors in DBMDR

Only blood donors can join DBMDR. Thus, all donors are recruited in blood banks and they meet the criteria for blood donors according to the EU directive for blood donation and the national Standards for Transfusion (TMS) in Denmark developed and maintained by the Danish Society of Clinical Immunology.

A donor is further characterized by:

- Age (year of birth) and gender
- ABO and Rh blood typing (performed by local blood banks)
- HLA typing data

New donors have since 2010 been HLA typed genomic for HLA-A, -B, -C, DRB1 and DQB1 by Histogenetics. Upon request DBMDR can perform high resolution genomic HLA-A, -B, -C, -DRB1, -DQB1, DRB3, DRB4, DRB5, DQA1 and DPB1 typing.
In addition, infectious disease marker analyses and ABO and Rh typing are always provided at time of verification typing and pre-donation workup. Infectious disease marker and other analyses are performed according to a standard list which is frequently updated. Further, additional analyses may be performed, if specifically requested.

As of February, 2014, the list of infectious disease marker and other analyses is as follows (additional test may be performed if requested or required):

- Hiv Ag/Ab
- CMV (IgM and IgG) antibody status
- HIV RNA (only at workup)
- Antibody screening for syphilis
- HBsAg
- Anti-HTLV I and II
- Anti-HBc (total)
- Anti-EBV IgG and IgM (only at workup)
- HBV DNA (only at workup)
- Toxoplasmosis antibodies (IgG and IgM, only at workup)
- Anti-HCV
- HCV RNA (only at workup)

All donors are recruited for both bone marrow and peripheral blood HSC donation, as well for lymphocyte donation in case of need for a donor lymphocyte infusion. The Collection can collect and provide all cell products.

A stem cell donation can be requested according to the DBMDR Guidelines for request for donation and subsequent donations. Please see the document at the DBMDR web site.

**Donor search for Danish patients**

DBMDR performs search for unrelated donor or cord blood for Danish patients on behalf of the 2 transplantations centers (National University Hospital in Copenhagen, and Aarhus University Hospital). The search process includes preliminary search requests to DBMDR and registries or cord blood banks around the world, including NMDP, “activation” of potentially HLA-matched donors for allelic typing or verification typing and selection of best donor or cord blood unit. Donors are regularly searched for in BMDW and through the EMDIS system.

Patients are included for donor search after approval by the Group for Allogeneic Stem Cell Transplantation according to criteria published by the Danish Society of Hematology.