

NORWEGIAN BONE MARROW DONOR REGISTRY NBMDR

Vision



- To achieve and maintain a position of an internationally recognised and accredited hematopoietic stem cell (HSC) donor registry with respect to high quality of donor data base and HLA typing, individualized, rapid, and reliable services, smooth donor workup and stem cell donation, and conscientious follow-up.
- To achieve and maintain a position of an active participant in national and international research projects, including research protocols for allogeneic HSC transplantation.
- Through the quickest possible way to identify matched unrelated donors or cord blood units for patients in Norway awaiting allogeneic HSC transplantation with an unrelated donor.

Mission

- To maintain a data base of 25,000 – 35,000 or more HLA typed volunteer HSC donors recruited among blood donors in Norwegian blood banks and in the blood bank of Reykjavik, Iceland, and to make these donors internationally 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 unit searches, a matched HSC donor or umbilical cord blood unit for more than 90% of the domestic patients awaiting an unrelated allogeneic HSC transplantation.

History and current status

NBMDR was originally established at Institute of Transplantation Immunology at Rikshospitalet University Hospital in 1990 after an initial donation from The Norwegian Cancer Society. The Norwegian Cancer Society has continued to finance NBMDR. Since 2000, the institute has been named Institute of Immunology (IMMI) after merging with Institute of Immunology and Rheumatology. In 2010, Rikshospitalet University Hospital merged with other university hospitals in Oslo to Oslo University Hospital. NBMDR is located at IMMI, Oslo University Hospital – Rikshospitalet.

NBMDR is the only registry of volunteer HSC donors in Norway. In addition to running the donor registry, NBMDR has since its start performed unrelated donor searches for all Norwegian patients on behalf of the transplantation centres at Oslo University Hospital – Rikshospitalet (Section for Blood Diseases, Dept. of Medicine, and Children's Department). All unrelated allogeneic HSC transplantations in Norway take place at Oslo University Hospital – Rikshospitalet.

NBMDR is a regular service unit within the Section of Transplantation Immunology at IMMI. Oslo University Hospital – Rikshospitalet is the legal owner of NBMDR.

International collaboration and certifications

The NBMDR is aiming at complying with standards, recommendations and guidelines of World Marrow Donor Association (WMDA; www.worldmarrow.org) as well as other international and national regulations.

NBMDR is a member of WMDA. NBMDR regularly submits HLA data of its donors to Bone Marrow Donors Worldwide (BMDW; www.bmdw.org). NBMDR is participating in the EMDIS system (European Matching and Donor Information System) (www.emdis.net). National Marrow Donor Program (NMDP, www.nmdp.org) accredited Rikshospitalet University Hospital as an HSC Transplant Centre 1995 and

as a HSC Collection Centre in 1997. NBMDR was accredited by NMDP as an HSC Donor Centre in 1997. Further, NBMDR is licensed by the Norwegian Directorate for Health (former Norwegian Directorate of Health and Social Affairs) as a tissue establishment according to the Norwegian regulation of April 7, 2006, 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). Finally, the Norwegian Data Inspectorate has given its approval for the data practice of NBMDR, both with respect to its function as a Donor Registry/Donor Centre, and for searching for unrelated donors for Norwegian patients.

Section of Transplantation Immunology at IMMI is accredited by European Federation of Immunogenetics (EFI; www.efiweb.org) for HLA typing and donor-patient transplantation immunology evaluation for organ and HSC transplantation.

NBMDR and collaboration with Norwegian blood banks

NBMDR has a formal agreement with all Norwegian blood banks and the Blood Bank in Reykjavik, Iceland, as well as with the Collection Centre (Dept. of Cellular Therapy, Oslo University Hospital – Rikshospitalet) and the two Transplant Centre units (Section of Blood Disease, Dept. of Medicine, and Children's Dept., both Oslo University Hospital – Rikshospitalet). The infectious disease marker analyses of donors as well as other blood test are performed at relevant laboratories at Oslo University Hospital – Rikshospitalet, all approved by the Norwegian Directorate for Health. ABO and Rhesus typing are performed at the blood banks. Blood collection, ABO typing and cross-matching for autologous erythrocyte transfusion following a bone marrow donation take place at the Blood Bank of Oslo University Hospital – Ullevål.

Recruitment of donors in NBMDR and collaboration with blood banks

The NBMDR donors, age 18 – 55, are recruited from blood banks throughout the country and from the blood bank of Reykjavik, Iceland. The donors are *recruited* at the age of 18 – 40 years. There are approximately 60 blood banks in Norway, and all are actively recruiting donors. In addition, the blood banks collect and ship blood samples to IMMI for HLA typing or to a Transplant Centre abroad for confirmatory HLA typing. The blood banks can, upon request, receive the HLA typing data of their own donor for use when HLA-identical platelet donors are searched for. In addition, NBMDR offers assistance in searching for HLA-compatible platelet donors in individual blood banks.

Blood bank personnel are continuously being trained through various courses arranged locally and by the NBMDR annual training courses held in Oslo in the end of January. One or two annual newsletters are mailed to all blood banks in addition to the NBMDR Annual Report and other informational letters when needed.

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

- The donor has been accepted as a blood donor and meets the national standards for blood donors (*Veileder for transfusjonstjenesten i Norge*) developed and published by the Norwegian Directorate for Health.
- The donor is between 18 and 40 years of age at time of recruitment (previously 18 – 45 years of age).
- A donor has given a written informed consent to participate in NBMDR.

A donor is removed from the NBMDR data base when:

- When a donor's health condition is listed in the exclusion criteria of the Assessment Tool at Recruitment (NMDP) and/or WMDA Recommendations for the Registration and the Management of Volunteer Donors, Including Guidelines for Donor Eligibility or equivalent publications.
- The donor is older than 55 years of age.
- 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 NBMDR

Donors are requested to provide an informed written consent when joining NBMDR, when blood samples are shipped to IMMI or to a Transplant Centre for confirmatory typing, and when asked to donate HSCs or lymphocytes. All participation in NBMDR 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, blood group, and cytomegalovirus (CMV) antibody status are revealed by the blood banks to NBMDR. These data are, together with the HLA typing data and donor unique identification (ID) number, filed in the NBMDR data system. Since NBMDR is an accredited NMDP Donor Centre, NMDP also gives the donors a unique NMDP ID number which are also filed in the NBMDR data system. ID number, HLA types, ABO types, CMV antibody status, gender and age is the only information in communication with centres around the world.

When NBMDR initiates a search for an unrelated donor for a Norwegian patient, the patient (or superiors when applicable) gives written informed consent to reveal name, date of birth, and gender together with HLA, ABO and CMV data for the search process.

NBMDR is a regular entity of Oslo University Hospital – Rikshospitalet. The NBMDR personnel, as well as personnel at the Collection Centre and other collaborating units at the Oslo University Hospital – Rikshospitalet, have signed a declaration of confidentiality. In addition, all persons working at the hospital, including NBMDR personnel, have an ID card to access restricted areas and rooms. Finally, NBMDR personnel have only access to the data file and NBMDR Data System through a secure log in procedure.

Characterisation of donors in NBMDR

Only blood donors can join NBMDR. Thus, all donors are recruited in blood banks. Thus, they meet the criteria for blood donors according to the national standards for blood donors (*Veileder for transfusjonstjenesten i Norge*) developed and published by the Norwegian Directorate for Health.

A donor is further characterised by:

- Age (year of birth) and gender
- ABO and Rh blood typing (performed by local blood banks)
- Positive or negative for CMV-specific antibodies if tested by the donor's local blood bank
- HLA typing data (performed at IMMI. IMMI is EFI accredited):
 - New donors are typed genomically for HLA-A, -B, C, and DRB1 molecules.
 - Upon request, NBMDR can perform high resolution genomic HLA-A, HLA-B, HLA-C, DRB1, DRB3, DRB4, DRB5, DQB1, and DPB1 typing.

In addition, infectious disease marker analyses and ABO and Rh typing are always provided at time of confirmatory 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 or required.

As of April 1, 2010, the list of infectious disease marker and other analyses is as follows (the list is subject to changes. Additional tests may be performed if requested or required):

- HBs Ag
- Anti-Hep B
- Anti-Hep C
- HCV-PCR (only at donor workup)
- HIV antigen
- HIV antibodies
- Anti-HTLV I and II
- Anti-CMV
- Treponema pallidum tests
- Anti-EBV (only at donor workup)
- Toxoplasma antibodies (only at workup)

All donors are recruited for both bone marrow and peripheral blood HSC donation, as well as for lymphocyte donation in case of the need for a donor lymphocyte infusion. The Collection Centre can collect and provide all cell products. A stem cell donation can be requested according to the NBMDR

Rules for Stem Cell Request Acceptance. For more information about donor policy, please see documents available at the NBMDR web site.

Donor search for Norwegian patients

NBMDR performs HSC donor search for Norwegian patients on behalf of the two Transplant Centre units at Oslo University Hospital – Rikshospitalet (Section for blood diseases, Dept. of Medicine, and Children's Dept). The search process includes preliminary search requests to NBMDR and registries or cord blood banks around the world, including NMDP, "activation" of potentially HLA-matched donors for allelic typing or confirmatory typing, including final retyping [of patient and HLA-matched donor(s)], recommendation of donor selection to the transplant physicians, and donor work-up requests. Donors are regularly searched for in BMDW and through the EMDIS system.

Patients are included for donor search by the National Group for Allogeneic Stem Cell Transplantation according to criteria published in the journal of the Norwegian Medical Association (*Tidsskriftet for den norske legeforening*).

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