EBMT Registry

Non-indication Diagnoses

Guide to the completion of the EBMT data collection form:

Nonindication_Diagnoses_v2.1

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EBMT Registry

EBMT Clinical Research & Registry Department

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Introduction

Please make sure you have already checked the **Introduction to the EBMT Registry Completion Guidelines** document latest version available under *Manuals and Reference Documents* section on EBMT website.

Non-indication Diagnosis

Date of diagnosis

Enter the date the disease was diagnosed.

Classification

Select the diagnosis classification that is appropriate and check the box next to it.

- **Acute leukaemia**: Acute leukaemia is a malignant disease that originates either in a lymphopoietic stem cell (Precursor lymphoid neoplasms (PLN), previously ALL) or in a hematopoietic stem cell or progenitor cell (acute myeloid leukaemia, AML);

Acute myeloid leukaemias (AML)

AML with myelodysplasia related changes?

In most cases, this classification applies to AML where an MDS, MPN or an MDS/MPN has been diagnosed beforehand. In a few cases, it applies to what looks as a de novo AML at the time of diagnosis, but which after further analysis of the bone marrow or after treatment for the AML, there is a suggestion that there could have been an undetected history of myelodysplastic syndrome (MDS).

Indicate whether AML with myelodysplasia related changes was diagnosed or not, tick the box **Unknown** if it is not known. If the answer is **Yes**, specify also if the patient was previously diagnosed with MDS or MDS/MPN in the subquestion.

Was there a previous diagnosis of MDS, MPN or MDS/MPN?

If the patient had a previous diagnosis of MDS, MPN or MDS/MPN, answer **Yes** and fill-in and submit respective indication diagnosis form in addition to the current form; otherwise, answer **No**. If it is unknown whether or not the patient had a previous diagnosis of MDS, MPN or MDS/MPN, check **Unknown**.

Note: *For AML with myelodysplasia related changes, if MDS, MPN or MDS/MPN was previously diagnosed, besides the Acute leukaemia form the corresponding indication diagnosis form for MDS, MPN or MDS/MPN must be filled in as well.*

Therapy-related myeloid neoplasia (old "secondary acute leukaemia")

Indicate whether therapy-related myeloid neoplasia (therapy-related myeloid neoplasms or t-MN) was diagnosed or not, tick the box **Unknown** if it is not known.

Therapy-related myeloid neoplasia arises as a late-effect of cytotoxic and/or radiation therapy for a primary diagnosis. Answer **Yes** if it is related to prior treatment, but not after a previous diagnosis of MDS, MPN or MDS/MPN.

- If the patient has therapy-related AML and did not undergo HCT/CT for the previous diagnosis, please complete the *non-indication diagnosis* form to record the previous diagnosis.
- If the patient has AML related to HCT/CT therapy treatment for the previous diagnosis, please complete the appropriate *indication diagnosis* form for this previous diagnosis.

Donor cell Leukemia :

For Therapy-related myeloid neoplasia, please specify whether this leukemia is on Donor cell of the previous Allogeneic transplantation, by answering the question “Is this a donor cell leukaemia?”

- **Autoimmune disorder**: Autoimmune disorders (ADs) are disorders where the body’s immune system attacks its own tissue;
- **Bone marrow failure:** Bone marrow failure syndromes are disorders of the hematopoietic stem cells leading to cytopenia that can involve one or more cell lineages. They can be acquired (non-constitutional) or genetic (constitutional);
- **Chronic leukaemia:** Chronic leukaemia is a malignant disease that originates from either the bone marrow, lymphocytes or prolymphocytes. It can be divided into chronic myeloid or chronic lymphocytic leukaemia. For the purposes of reporting anonymous events, prolymphocytic leukaemia can be reported as ‘other’;
- **Haemoglobinopathies** are a heterogeneous group of inherited diseases characterised by alteration of haemoglobin production;
- **Lymphomas** are malignant neoplasms of the lymphatic system, which includes lymph nodes, spleen, thymus, Waldeyer’s ring, appendix, and Peyer’s patches. Lymphomas are divided into two subgroups: Hodgkin lymphoma (HL) and Non-Hodgkin lymphomas (NHL);
- **Myelodysplastic syndrome/myeloproliferative neoplasm** (MDS/MPN) are a group of chronic clonal myeloid malignancies in which there are features of both MDS and MPN at the time of presentation. This category was originally composed of the following major myeloid disorders: chronic myelomonocytic leukaemia (CMML), juvenile myelomonocytic leukaemia (JMML),

MPNMDS with ring sideroblasts and atypical chronic myeloid leukaemia (aCML). Myeloid disease that shows features of both MDS and MPN but does not meet the criteria for any of the major MDS/MPN entities is designated as myelodysplastic/myeloproliferative neoplasm, unclassifiable (MDS/MPN-U);

- **Myelodysplastic neoplasms** (MDS) is a heterogeneous group of clonal haematopoietic stem cell disorders characterised by ineffective, dysplastic haematopoiesis, peripheral cytopenia and a variable rate of progression to acute myelogenous leukaemia (AML);

Therapy-related MDS

Indicate if MDS developed due to medical treatment (therapeutic agents or radiation).

Is this a donor cell leukaemia?

If therapy- related MDS is Yes, please indicate if it was a donor cell derived leukemia. If there was no prior transplant please select **Not applicable (no previous allo HCT).** If it is not known whether or not it was a donor cell derived leukemia, select **unknown.**

- **Myeloproliferative neoplasms** (MPNs) include a group of haematological disorders originating from a pluripotent stem cell of haematopoiesis that typically present with a hypercellular bone marrow with fibrosis, hepatomegaly, splenomegaly, and increased blood cell counts (cytopenias are possible);
- **Plasma cell neoplasm (PCN):** Plasma cell neoplasms are related to an overproduction of plasma cells in the body and subsequently a possible overproduction of immunoglobulins;
- **Solid Tumour:** Solid Tumours are a group of malignancies presenting with masses internal or external to organs such as breast, ovarian or lung carcinoma.

Subclassification

The subclassification needs to be reported in different levels of detail for different diagnoses. For instructions on selecting the appropriate classification, consult the completion guidelines for the diagnosis you want to enter data for.