

Guidelines for reporting data to the EBMT Activity Survey 2016.

Table 1: Number of patients receiving their 1st allograft or their 1st autograft in your centre in 2016.

Report the first allogeneic transplant and/or first autologous transplant per patient according to disease indication, donor type and stem cell source as outlined in Table 1. You may include the same patient twice as long as the first occurrence of each type of transplant took place in 2016. Patients without consent to share data can also be reported to the survey.

Note: The transplant procedure starts at conditioning. If a patient dies immediately after being given the cells or immediately before being given the cells, the patient is still dying within the transplant procedure and must be reported.

The following EBMT/JACIE/FACT definitions for 'first transplants' apply:

- first transplant (new patient, never transplanted before)
- first allograft (after a previous autograft) or first autograft (after a previous allograft)
- first allograft or first autograft in your centre after a previous transplant in a different centre.

Disease classification: the classification of diseases for the survey follows the WHO classification of tumors of hematopoietic and lymphoid tissues and the EBMT disease classification dictionary, which can be found at: www.ebmt.org – Research – survey submission –List of Disease Classifications.

NEW: The following definitions for donor type apply:

HLA id sibling: HLA identical sibling.

Haplo (≥ 2 loci mismatch): any family member with 2 or more loci mismatch within the loci HLA-A,-B,-C,-DRB1 and -DQB1 in GvH and/or HvG direction.

Other family member: any other family member who is not included in the definition above.

For combinations of stem cell products report as follows:

- Bone marrow and peripheral blood = peripheral blood stem cell transplant - enter as PBSC
- Bone marrow and cord blood = cord blood transplant - enter as Cord
- Peripheral blood and cord blood = cord blood transplant - enter as Cord
- Bone marrow and peripheral blood + cord blood = cord blood transplant - enter as Cord

Additional information

- For Twin: report both BM and PBSC together.
- Autologous stem cells given together with an allogeneic transplant within 7 days = allogeneic transplant.
- Multiple infusions of the same product, e.g. double cord, multiple cord, multiple PBSC, within one week should be reported as one transplant only.
- Re-infusion of allogeneic stem cells for graft failure is considered to be an additional transplant, enter in Row 30.
- Re-infusion of autologous stem cells for non-engraftment is considered to be a boost and is not a transplant.
- Non transplant allogeneic/autologous stem cell boosts given for graft enhancement, enter in Row 36 - other.
- An allo boost is an infusion of cells from the same donor without conditioning, in the presence of engraftment, with the same donor being present in a proportion higher than 10%. If cells are not from the same donor OR there is conditioning OR donor cells are present at a lower proportion than 10%, then it is a genuine transplant.
- A new transplant performed using a different donor or cell source is considered to be a retransplant, enter in Row 30.

Row 29: Number of patients receiving their 1st allograft or 1st autograft in 2016

Row 30: Number of additional transplants (non 1st HSCT) due to graft failure, relapse, other events or those that are part of planned multiple transplant protocols. Report only those that were given in 2016.

Row 31: Grand total of all transplants performed in 2016 reported in rows 1-28 + 30.

Row 32: Number of pediatric patients (<18 at transplant) and receiving their 1st allograft or 1st autograft in 2016 as reported in row 29.

Row 33: Number of patients receiving DLI infusions. Report the main reason, if more than one exists, for giving the DLI at the time of infusion. The year the transplant was done does not affect the DLI reporting itself.

Row 34: Number of transplants with non myeloablative conditioning reported in row 31.

No. allo after auto: refers to the number of patients who receive their 1st allograft after a previous autograft in 2016. Enter both the 1st allograft and 1st autograft (when applicable) in table 1 by indication and donor type. In addition enter the total number of these allografts in the column '*No. allo after auto*' on the right side.

NEW Table 2: Number of patients receiving Non-HSCT Cellular Therapies in your centre in 2016.

Report the number of patients receiving NON-HSCT Cellular Therapies in your centre in 2016 by indication for which the therapy is being given and cell type. Both patients with or without transplants can be reported in Table 2.

Note: CD34⁺ selected transplants or for example CD3⁺/CD19⁺ deleted cell infusions are to be reported as transplants in Table 1.

MSC: mesenchymal stromal cells

NK cells: cells used for DLI that are processed after harvesting by selecting for NK cells with or without expansion or genetic modification

Selected/expanded T-cells or Cytokine Induced Killer cells (CIK): T-cells selected, expanded in vitro, cytokine activated either given as DLI or in other conditions are reported here, this excludes genetically modified T-cells

Regulatory T cells (TREGS): T cells used for DLI that are processed after harvesting by selecting for the subset of regulatory T-cells

Genetically modified T-cells: T-cells that are genetically modified by viral or non-viral vector to express chimeric antigen receptors or T-cell receptors (CAR-T/TCR) or genetically modified T-cells with suicide genes or other genes.

Dendritic cells: antigen presenting cells that are used for tumor cell vaccination and other purposes

Expanded CD34⁺ cells: Stem cell products that are expanded in vitro prior to infusion to the patient

Genetically modified CD34⁺ cells: Genetically modified stem cells, typically used for congenital diseases.

Other: any other cellular therapy not listed above.

Cellular therapies reported in Table 2 given for autoimmune disease, genetic disease, infection or malignancy may be with or without a previous transplant. A follow-up survey sheet will be sent later during the year to specify treatments given for regenerative medicine.