

Program Information Section

Q. What does “Inception Date” mean?

A. The inception date is the date the first transplant of that type was performed.

Q. If a patient has received a tandem transplant or an allogeneic transplant after an autologous transplant, how should the data be recorded in Table A-2 and Table A-4?

A. If a patient receives a tandem transplant, it should be reported only once, in the year in which the first transplant occurred. If a patient received a 2nd transplant < 365 days from the 1st transplant, report the patient only in the category of the 1st transplant. If a patient received a 2nd transplant > 365 days from the 1st transplant, report both transplants in the appropriate years and categories.

Q. Our tandem transplant program began in 1996 and lasted until 2007, so our data are not fully captured in Table A-7 [Tandem Transplants]. What should we do?

A. The tables in the Program Information section are for capturing recent transplant activity. If you'd like to include your program's full history of tandem transplants, you can include that information in your response to Question F-3.

Q. How does table A-2 differ from table A-12?

A. In table A-2 the number of patientstransplanted should be reported. Use the Multiple Transplant Grid as a guide.

In Table A-12 the number of transplantprocedures should be reported. Report each transplant.

Q. For the tables is A-2, A-4, and A-12 how is Antigen defined?

A. The antigen match/mismatch is based on a denominator of 8. Class I + DRB1 antigen matches/mismatches should be reported. Do not report matches/mismatches at DRB3, 4, 5 and DQB1.

Outcomes Data Section

Q. Where can I find the Definition tab mentioned in the Read Me notes?

A. The Outcomes Data section is an Excel spreadsheet with 5 worksheets (tabs). These tabs can be found at the bottom of the spreadsheet. In some cases when the spreadsheet is downloaded from the web site, it opens to the worksheet that is located to the far right. You can scroll or use the arrow button to move to the left in the spreadsheet and see all 5 of the worksheets.

Q. In the Definition for Total Patients, it says tandem transplants should be counted once. That makes sense for Auto/Auto transplants. However, when an Auto/Allo is performed, should each transplant be counted separately?

A. If it is a planned tandem transplant (i.e. the second transplant is planned in advance at the time of the first transplant), it should be reported only once, in the category of the first transplant. If two transplants are performed within 365 days of each other, they should be counted only once, in the year and type of the first of the two transplants. Patients who receive a 2nd transplant > 365 days after their 1st transplant should be reported in each of the appropriate categories and types of transplants. If the two transplants were of the same type, count in the cumulative years column only once and footnote what's been recorded. If the transplants are of different types, report in both cumulative years columns; again, footnote what's been recorded.

You might also refer to the ASBMT RFI Second Transplant Grid on the ASBMT web site for additional information on how multiple transplants should be categorized.

Q. A patient receives an autologous transplant and 200 days later receives a second autologous transplant. How should this patient be reported?

A. The patient is reported once in the disease category for which the first transplant was performed. Survival is calculated using the date of the first transplant.

Q. A patient receives an autologous transplant and 400 days later receives a second autologous transplant for a different disease. How should this patient be reported?

A. The patient is reported in both years; included in the survival calculation for both years; but included only once in the cumulative column. A footnote should be provided to explain the discrepancy between the total number of patients in each year and the total number of patients used in the cumulative column.

You might also refer to the ASBMT RFI Second Transplant Grid on the ASBMT web site for additional information on how multiple transplants should be categorized.

Outcomes Data Section (cont'd)

Q. A patient receives an autologous transplant and 400 days later receives an allogeneic transplant. How should this patient be reported?

A. The patient is reported in both years; included in the survival calculation for both years; and included in the cumulative column for both years. A footnote should be provided to explain that the patient is reported in two categories.

You might also refer to the ASBMT RFI Second Transplant Grid on the ASBMT web site for additional information on how multiple transplants should be categorized.

Q. In the Survival Statistics by Disease tables, does the “# column” refer to the number of patients surviving to that time point or to the total number of transplants performed for that disease type?

A. The “Total #” column refers to the total number of patients transplanted in that risk category for the disease type indicated. The “100 day #” column refers to the total number of patients surviving at the 100 day time point in that risk category for the disease type indicated. The “100 day %” column refers to the number of patients alive at 100 days divided by the total number of patients transplanted in that category (e.g. 100 day # / total #). This same definition is true for the “1 year #” and “1 year %” columns.

Q. What does “actual survival” mean?

A. Actual survival is the number of patients in that category who are alive, divided by the total number of patients in that category. The previous version of the RFI requested Kaplan Meier analysis and actuarial survival calculations. BMT RFI no longer requires the Kaplan Meier analysis.

Q. Should we report the patients’ risk category at the *time of diagnosis* or at the *time of transplant*?

A. Report the patient’s risk category at the time of transplant.

Q. In the Adult Clinical Statistics spreadsheet and the Adult Survival by Disease spreadsheet, the 2013 data are through 9/30/13. Shouldn’t this be through 12/31/13?

A. 2013 data are reported on patients whose transplants occurred on or prior to 9/30/13. Note that 100-day survival is requested, not one-year survival. Commutative data should be reported for 2010-2012. Do not include 2013 in the commutative data since complete one-year survival would not be available.

Outcomes Data Section (cont'd)

Q. How should I report the diagnosis when the patient had more than one of the diagnoses listed?

A. Report the primary disease or diagnosis that necessitated the transplant. Secondary disease that has resulted from the primary disease should not be recorded.

Q. How should I report a diagnosis that is not listed in the table?

A. Diseases that are not listed in the table should be recorded in the diagnostic category that is the most comparable. For diseases that are not comparable to any of those listed, record the number in the OTHER category.

Q. How should I report patients who have been lost to follow-up?

A. The Clinical Statistics data tables request the number of patients lost to follow-up within the first 100 days and between 100 days and 1 year. These are patients whose survival status is unknown. These patients should be included in the total number of patients but should be excluded from the survival calculation. For example, if there are 10 patients and 1 dies and survival status of 2 others is not known, the actual survival value will be $(10-1-2)/(10-2) = 7/8$ or 87.5%.

The 100-day survival calculation should exclude patients lost to follow-up before the 100-day time point only. It should not exclude those lost to follow-up between 100 days and 1 year. The one year survival calculation should exclude those patients lost to follow-up anytime before the 1 year time point.

Data on patients lost to follow-up is not requested in the Survival Statistics by Disease data tables, but as with the Clinical Statistics, patients whose survival status is unknown should be excluded from the survival calculation on the Survival Statistics by Disease data tables.

Q. How should syngeneic transplants be reported? (A syngeneic transplant uses cells from an identical twin.)

A. A syngeneic transplant should be reported as a related allogeneic transplant.

Q. In terms of the HLA matching categories, does mismatch by > 1 antigen include any mismatch at the following loci: Class I-A, B, C and Class II-DRB1, DRB3, DRB4, DRB5 and DQB? For example, if there is a mismatch at B and at DRB1, would that be a two-antigen mismatch?

A. For allogeneic-related and unrelated transplants, the antigens to report include Class I (HLA A, B, C) and DRB1 (8/8). If there is a mismatch at B and at DRB1, that would be a two-antigen mismatch. Antigen matches/mismatches at DRB3, 4, 5 and DQB1 are not included in what should be reported.

Date created: 3/4/03

4 of 8

Date(s) of Revision: 2/27/04; 12/1/04; 11/17/05; 10/23/06; 11/15/07; 9/26/09; 10/18/10, 11/23/11, 11/4/12, 12/3/13; 1/13/14; 2/17/15

Outcomes Data Section (cont'd)

Q. Some of the patients transplanted at our center fit into more than one of the TRANSPLANT TYPE categories. How should they be reported?

A. The TRANSPLANT TYPE categories are intended to be mutually exclusive. Each patient should be reported only once under the transplant type that most accurately reflects the graft. The categories for both the clinical statistics and the survival statistics tables are as follows:

- Autologous
- Allogeneic Myeloablative Related Donor, 0 Antigen Mismatch Donor
- Allogeneic Myeloablative Related Donor, ≥ 1 Antigen Mismatch Donor
- Allogeneic Non-Myeloablative Related Donor, 0 Antigen Mismatch Donor
- Allogeneic Non-Myeloablative Related Donor, ≥ 1 Antigen Mismatch Donor
- Allogeneic Myeloablative Unrelated Donor, 0 Mismatch
- Allogeneic Myeloablative Unrelated Donor, 1 Mismatch
- Allogeneic Myeloablative Unrelated Donor, > 1 Mismatch
- Allogeneic Non-Myeloablative Unrelated Donor, 0 Mismatch
- Allogeneic Non-Myeloablative Unrelated Donor, 1 Mismatch
- Allogeneic Non-Myeloablative Unrelated Donor, > 1 Mismatch
- Allogeneic Cord Blood Donor (includes related and unrelated)

Q. Should data related to patients who received reduced intensity regimens be included with the non-myeloablative regimen data or with the fully ablative regimen data?

A. Data related to patients who received reduced intensity regimens should be included with the non-myeloablative regimen data for the appropriate transplant type.

Q. Where do I record patients who had no conditioning? For example, we transplanted a patient with SCIDs who received no conditioning.

A. Include in appropriate non-myeloablative group.

Diagnosis Categories

Note: Available on the ASBMT web site is a document that provides assistance in translating the CIBMTR classifications to the ASBMT RFI disease risk categories.

CML (Adult)

- Q. How should patients in a risk category greater than CP2 be categorized?**
- A. Patients in greater than CP2 should be in the HIGH RISK category.
- Q. Regarding the INTERMEDIATE RISK category “CP2 and Accelerated Phase,” what does “accelerated phase” mean? Is it *first* accelerated phase, *second* accelerated phase, or *all kinds* of accelerated phases?**
- A. The INTERMEDIATE RISK category can include first and/or second accelerated phase.
- Q. Does the HIGH RISK “Blast phase” refer to the *first* blast phase or *all kinds* of accelerated phases?**
- A. The diagnosis at time of transplant should be reported. Usually “blast phase” is clearly blast phase, and “accelerated phase” is clearly accelerated phase.
- Q. How should patients in “CP1 bcr/abl present” be categorized?**
- A. These patients should be reported in the LOW RISK category
- Q. Is “accelerated phase” limited to AP1 or can any accelerated phase be included?**
- A. Accelerated phase should be limited to AP1. These patients are reported in the INTERMEDIATE RISK category.
- Q. Where should I report a patient in CP3/+?**
- A. These patients should be reported in the HIGH RISK category.

CLL (Adult)

- Q. There is no category listed for patients in PR. In which risk category should these patients be placed?**
- A. Patients in first PR should be in the LOW RISK category. If greater than first PR, that data should be recorded in the HIGH RISK category.

Diagnosis Categories (cont'd)

MDS (Adult)

Q. In what category should a patient with unclassified, non-specific MDS be reported?

A. If unclassified, categorize the patient based on the prognostic factor index of MDS. (The transplant program physician should choose the category).

Q. In what category should a patient with MDS-NOS be reported?

A. If NOS with < 5% blasts, report in the LOW RISK category. If NOS with 5% blasts, report in the HIGH RISK category.

Hodgkin's Disease (Adult)

Q. How should a patient in PR1 be reported?

A. A patient in PR1 should be reported in the INTERMEDIATE RISK category.

Q. How should a patient with "sensitivity unknown" be reported?

A. A patient with sensitivity unknown should be reported in the INTERMEDIATE RISK category.

NHL (Adult)

Q. In what category should a patient with > CR1 be reported?

A. Base the risk group category on the reason for the relapse. If in CR2 following chemo sensitive relapse, place the patient in the INTERMEDIATE RISK category. If in CR2 but with resistant disease, place the patient in the HIGH RISK category.

Q. How should a patient in PR1 be reported?

A. A patient in PR1 should be reported in the INTERMEDIATE RISK category.

Q. How should a patient with "sensitivity unknown" be reported?

A. A patient with sensitivity unknown should be reported in the INTERMEDIATE RISK category.

Diagnosis Categories (cont'd)

Myeloma (Adult)

- Q. There are no categories for patients with no response/stable disease and for patients with minimal response. How should each of these types of patients be reported?**
- A. Both these patient types should be reported in the HIGH RISK category.
- Q. If a patient's disease status can't be described in any of the risk categories listed, should that patient just be excluded from the survival statistics tables?**
- A. No, do not exclude patients from the analysis. Report them in the risk category that most closely fits their situation or if none fit, add an "other" category on the spreadsheet for that data and make a narrative notation at the bottom so the payer can track what has been reported.
- Q. There are no disease categories for breast cancer patients. Where should these patient outcomes be reported and should they be separated into risk categories (stage II/III, IV, inflammatory)?**
- A. Breast cancer patient survival can be reported under the OTHER SOLID TUMOR category. Risk categories of stage II/II, stage IV, and inflammatory disease can be listed.

Neuroblastoma (Pediatric)

- Q. Where should a patient in PR1 be reported?**
- A. A patient in PR1 should be reported in the INTERMEDIATE RISK category.