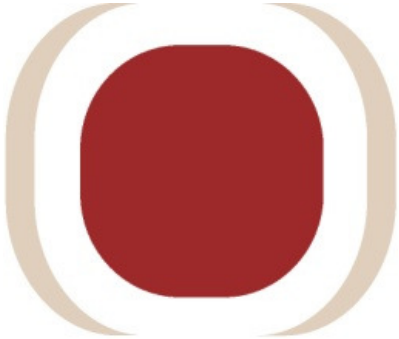

ABMTRR
Australasian
Bone Marrow Transplant
Recipient Registry

Guidelines for completing Annual Follow Up Form (Form B)

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INTRODUCTION

The Annual Follow-Up Form (Form B) replaces both the ABMTRR Patient Follow-Up Form B and the Annual Update for 1 – 5 years post transplant (Form UB), used by Australian MUD centres.

Who should use these forms?

These forms should be submitted for:

- every transplant recipient transplanted from 2013 onwards by all centres.
- Unrelated donor transplants from Australian centres from 2008 transplants onwards. It is still a requirement that all Australian MUD centres complete these annually up to the first 5 years after transplant.

When should these forms be submitted?

Annual Follow Up Forms Submission of the Annual Follow Up Form may be made annually on or after the anniversary of the recipient's transplant date or on an ad-hoc basis whenever an event occurs.

The information provided should be within the follow up period, including events **since the last report**. Any "latest" dates of events should be as close to the anniversary date as possible.

If another transplant occurs during a follow up period, then any events should be reported up to the day before conditioning therapy is commenced. If no preparative conditioning is planned, then the reporting period will include up to the day before the subsequent infusion date. Another registration form and associated follow up will then be required for the subsequent transplant. No further follow up will be required for the previous transplant.

How to submit forms

Annual Follow Up may be submitted on the paper form (Form B) and sent to ABMTRR either by post or emailed as an attachment, or online via ASTRO.

Date format: All dates are reported as dd/mm/yy

Patient/Transplant identification

Hospital

Patient UPN

Patient name identifier

Date of Birth

Transplant date

Details given in these fields should match those provided on the Registration Form (Form A).

Follow Up period: Year ____ post transplant.

Insert the number of years post transplant the report is for.

1. Survival Status

Indicate the recipient's survival status at the most recent contact or correspondence.

Last known date of contact/death.

Report the last known date that the patient was alive or the date of death.

This date is used in survival analyses and it is important to have this updated annually (for alive recipients) if known.

The date may be different from the "Last known disease status date" (Question 1a.) if the disease status was not assessed at time of last contact.

If the recipient has not been seen by a physician and survival status is known, this should be reported

Date may be approximated if the exact date is not known.

Main cause of death

Report the underlying cause of death... the underlying cause of death is "the disease or injury that initiated the chain of events that led directly or inevitably to death." *Ref: CIBMTR Forms Manual: Recipient Death Data Form 2900 Document Number: A00564 version 1*

Examples:

- If an infection leads to heart failure, the infection should be reported as the primary cause of death.
- If the patient dies of acute renal failure which was associated with progressive myeloma, then the myeloma should be reported as the primary cause of death.

Report only one main cause of death, however contributing causes may be listed, under "Comments", if relevant. Do not report the mode of death eg cardiac or respiratory arrest.

If the recipient has recurrent/persistent/progressive disease at the time of death, consider if the disease was the primary cause of death or a contributing cause of death. One should not assume that the presence of disease indicates that the disease was the primary cause of death.
It may be reported on a post mortem as the primary cause, however, for registry reporting, use the criteria below to help determined how to report this.

- **Disease is present and progressing:**
  In the presence of clinical disease, if the disease is progressing, the main cause of death should be reported as **"Relapse/Progression/Persistent disease",** regardless of any accompanying complications or infections during the post-transplant period.
- **Disease is present and stable or improving:**
  In the presence of clinical disease, and the disease is stable or there had been an improvement after transplant, and the patient were to die of complications or infections, then the main cause of death would then be the complication or infection. The cause of death would be reported as "**Treatment related"**, then indicating all the causes as appropriate by ticking the relevant checkboxes. (see below)

Treatment related causes

☐ Transplant related (select as many as appropriate)

☐ GvHD	☐ Cardiac toxicity
☐ Infection	☐ Pulmonary toxicity
☐ Rejection/poor graft function	☐ VOD
☐ Other, specify_____	

New malignancy
If the recipient dies of a new malignancy, ensure that the details of the malignancy have been reported.

If the main cause of death is a malignancy that was diagnosed prior to the transplant, then report this under "Other, specify"

If the malignancy is considered a progression of the disease for which the transplant was for, then the main cause of death should be reported as "Disease progression" rather than a new malignancy, eg. transplant indication was MDS, then the disease progresses to AML post transplant.

Note: Aplastic anaemia
If a recipient was transplanted for aplastic anaemia and dies of relapsed disease, then the cause of death should be reported as "Rejection/poor graft failure" (under "Transplant related" causes).

Other, specify

Select this option only when the other available options are not appropriate.

1a. Last known disease status

Completing this section allows more precise analysis of patient status, when assessing patient outcome or survival.

Previously, as ABMTRR collects first incidence of relapse or progression only, there had been no record of an updated disease status to help with analyses.

Assessment of the disease status may be a clinical assessment, including correspondence from a physician, radiological, or laboratory test (FBE, biochemistry, cytogenetic, flow cytometry, molecular)

The "Date assessed" may not be the same as the "Last known date of contact".

2. Best disease status achieved post transplant, prior to treatment modification

(not relevant for non-malignant diseases)

Report the recipient's best response to the planned course of the transplant. This does not include response to any treatment given for relapsed or persistent disease that was not a planned part of the transplant.

If the recipient was in complete remission at the time of transplant, then the only possible response will be "Continued complete remission".

Recipients not in complete remission at the time of transplant who achieve CRU (Complete remission unconfirmed – persistent scan abnormalities of unknown significance) should be reported as "Complete remission achieved". Include the date assessed.

Refer to the definition of Complete Remission for the specific disease classification.

If the recipient was not in complete remission at the time of transplant, and has persistent or residual disease during the 100 days post transplant, then select "Never in complete remission" Include the latest assessment date in the report.

2a. Did graft failure occur?

Graft failure includes persistent neutropenia, <5% donor chimerism, and ANC $<0.5x10^9$/L for three or more consecutive laboratory values.
Graft failure often requires an additional infusion of donor cells and may result from the use of specific drugs, infection (especially CMV), GVHD, as well as other causes.

3. First Relapse or Progression post transplant

Only report the **first** relapse or, in the case of persistent or residual disease, the **first** indication of disease progression.

Detection methods include clinical/haematological, cytogenetic, and molecular.

Clinical assessment includes radiological and physical assessments eg. the recipient is evaluated by the physician.

Flow cytometry may be included as cytogenetic assessment.

Only the first instance of each detection method should be reported.

If First relapse/progression has been reported in an earlier report, then tick the "previously reported" checkbox.

If relapse or progression has not occurred, then report the latest date the disease was assessed in the space provided. If the patient has never relapsed after transplant and was in CR at their last assessment, then this date will be the same as reported in question 1a.

4. New malignancy, lymphoproliferative or myeloproliferative disorder post transplant

Include:

- Skin cancers
- Post transplant lymphoproliferative disorders
- Benign conditions, with the potential of developing into a malignancy eg. CIN (early stages), pleomorphic adenoma

Do not report:

- transformation of the primary disease (Primary disease being the disease for which the transplanted was indicated for)
- progression of the primary disease eg. plasmacytoma develops into myeloma
- recurrence of a prior malignancy, (malignancy reported in the pre-transplant history)

Any conditions that you are unsure if they should be included may be entered for review by ABMTRR.

5. Performance Status at this year's follow-up

Use Karnofsky (patients 16 years and older) or Lansky score (patient less than 16 years)

Use this scale to determine the score (10-100) that best represents the recipient's activity status at the requested time point.

	Karnofsky Scale (recipient age≥16 years)	**Lansky Scale** (recipient age <16 years)
(80–100)	*Able to carry on normal activity; no special care is needed*	*Able to carry on normal activity; no special care is needed*
100	Normal, no complaints, no evidence of disease	Fully active
90	Able to carry on normal activity	Minor restriction in physically strenuous play
80	Normal activity with effort	Restricted in strenuous play, tires more easily, otherwise active
(50–70)	*Unable to work, able to live at home cares for most personal needs, a varying amount of assistance is needed*	*Mild to moderate restriction*
70	Cares for self, unable to carry on normal activity or to do active work	Both greater restrictions of, and less time spent in active play
60	Requires occasional assistance but is able to care for most needs	Ambulatory up to 50% of time, limited active play with assistance/supervision
50	Requires considerable assistance and frequent medical care	Considerable assistance required for any active play, fully able to engage in quiet play
(10-40)	*Unable to care for self, requires equivalent of institutional or hospital care, disease may be progressing rapidly*	*Moderate to severe restriction*
40	Disabled, requires special care and assistance	Able to initiate quiet activities
30	Severely disabled, hospitalization indicated, although death not imminent	Needs considerable assistance for quiet activity
20	Very sick, hospitalization necessary	Limited to very passive activity initiated by others (e.g. TV)
10	Moribund, fatal process progressing rapidly	Completely disabled, not even passive play

Audit status: Estimate or documented?

Indicate if the Performance Score has been documented in the recipient's notes or correspondence (Documented) or derived from the notes or correspondence (Estimated)

ALLOGRAFT SECTION

6. Chronic Graft versus Host Disease

Indicate if the patient developed chronic GvHD

Date of first incidence of chronic GvHD
Report the first incidence only

If this has been reported in an earlier follow up, then tick the "previously reported" checkbox.

Was cGvHD present during this period?
This only applies to this follow up period. If yes, then complete the remaining section.

Note: the follow up period will commence from the previous year's report up to the next anniversary of the recipient's transplant if reported annually, otherwise the follow up period will be since the last report to the next anniversary date of the transplant.

Maximum extent of chronic GvHD

Indicate the maximum extent of chronic GvHD during this reporting period using following criteria (Sullivan KM, Blood 1981: 57:267)

Limited: Localised skin involvement resembling localised scleroderma with or without liver involvement No other organ involvement
Extensive: Generalised skin and/or multiple organ involvement

Organs affected

Tick as many checkboxes as applicable to include all the organs that were affected during the follow up time period.

7. Donor cellular infusion (DCI)

Report any donor cellular infusions given to the recipient up to the first year post transplant.

Note: If additional cells are given for failed or poor neutrophil recovery, loss of graft or late graft failure, ie. the intent is to repopulate the recipient's marrow with haematopoietic cells, then this should be reported as a transplant.

Please indicate if additional cell therapy was given. If yes, complete the following.

First infusion date
Report the date of the first infusion only.

Cell type
Donor cell types include but not limited to:

- Lymphocytes
- Mesenchymal cells
- Dendritic cells
- Peripheral blood mononuclear cells, stimulated and unstimulated

Indication
DCI is a form of immunotherapy with cells donated from any donor. It may be used for (but not limited to):

- treatment of recurrent disease, by inducing a graft versus leukaemia /tumour effect
- pre-emptive treatment in cases of high risk of disease relapse
- treatment of GvHD
- promote engraftment when chimerism studies show less than 100% donor cells
- conversion of mixed chimerism to full chimerism
- treatment of infections eg. viral
- treatment of B cell lymphoproliferative disorder - PTLD or EBV lymphoma

REFERENCES

1. Center for International Blood and Marrow Transplant Research (CIBMTR) Forms Manuals:
   - 100 Days Post-HSCT Data Form 2100: A00531 version 1.1
   - Post-TED Form 2450: A00425 version 2.0
   - Pre-TED Form 2400: A00413 version 2.3
   - Recipient Death Data Form 2900**:** A00564 version 1

2. MED-AB Forms Manual. A guide to the completion of the EBMT HSCT Med-AB Forms 2010. European Group for Blood and Marrow Transplantation. (Last modified 17/07/2012)