

Section XI - Pediatric Bone Marrow/Stem Cell Transplant

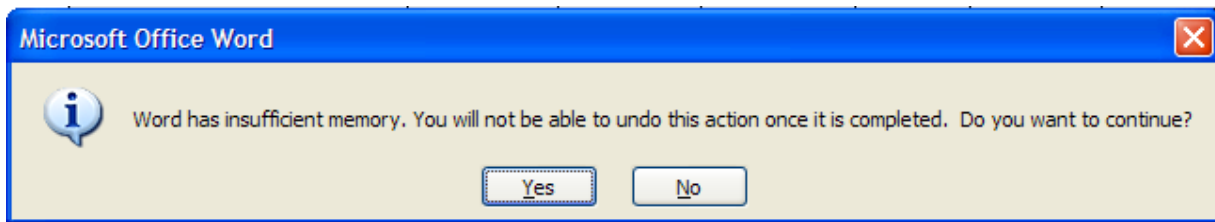
PART 1: ASBMT Standardized RFI

All facilities interested in being considered for participation, or currently participating in, the BDCT for bone marrow/stem cell transplant must complete the **ASBMT 2008 Standardized RFI** Transplant Administrative Survey and Program Information RFI. Please go to <http://www.asbmt.org/rfi/form.html> to download and complete the ASBMT RFI. Please note that facilities are not required to complete the Outcomes Data spreadsheet within the ASBMT RFI for the BDCT process.

If your facility is a free-standing transplant center and does not directly provide inpatient services, a **SECOND** General Section (Section I) must be completed by the facility at which inpatient services are/would be provided.

PART 2: Please complete the following questions pertaining to your Pediatric Bone Marrow/Stem Cell transplant program. If there are any questions, please contact Andrew Love at 312.297.6109 or send an email to transplant@bcbsa.com.

- You may “tab” through data entry fields or use your mouse to move the cursor to the desired field.
- At various times within this document, you may encounter the following pop-up box (shown below as an example). Please Click ‘Yes’ when the pop up box appears, and continue with your data entry.



1. Please indicate the number of **AUTOLOGOUS** transplants performed in the following age groups from January 1, 2005 through December 31, 2007. Each tandem/multiple/re-transplant should be counted as an individual transplant. Include all inpatient and outpatient transplants.

The volume reported should correlate with the number of transplants of this type reported in the Section XI - Appendix B - Pediatric Auto/Allo Patient Data Table for 2005, 2006, and 2007.

Age of Patients	# of Transplants 2005	# of Transplants 2006	# of Transplants 2007
< 1			
1-5			
6-10			
11-17			
TOTAL	0	0	0

2. Does your facility collect and report outcomes data on all autologous bone marrow/stem cell transplants to the CIBMTR?
 YES NO

3. Please indicate the number of **ALLOGENEIC** transplants performed in the following age groups from January 1, 2005 through December 31, 2007. Each tandem/multiple/re-transplant should be counted as an individual transplant. Include all inpatient and outpatient transplants. Include all non-myeloablative transplants. **Any procedure not preceded by conditioning therapy and followed by BMT/stem cell transplant (i.e. additional cell support for graft failure and/or donor leukocyte infusions (DLI)) should NOT be counted.

The volume reported should correlate with the number of transplants of this type reported in the Section XI - Appendix B – Pediatric Auto/Allo Patient Data Table for 2005, 2006, and 2007.

Patient Age	# of Transplants 2005			# of Transplants 2006			# of Transplants 2007		
	Related Matched and Mismatched BM/PBSC	Unrelated Matched and Mismatched BM/PBSC	Cord Related and Unrelated Matched and Mismatched	Related Matched and Mismatched BM/PBSC	Unrelated Matched and Mismatched BM/PBSC	Cord Related and Unrelated Matched and Mismatched	Related Matched and Mismatched BM/PBSC	Unrelated Matched and Mismatched BM/PBSC	Cord Related and Unrelated Matched and Mismatched
< 1									
1-5									
6-10									
11-17									
TOTAL	0	0	0	0	0	0	0	0	0

4. Please indicate the total number of all non-myeloablative transplants included in the volume reported in Question #3.

	# of Transplants 2005	# of Transplants 2006	# of Transplants 2007
TOTAL			

5. Complete the following data table for ALL pediatric patients undergoing Bone Marrow/Stem Cell transplant from January 1, 2006 through December 31, 2007.

Autologous	2006	2007
Number of patients who expired after the start of conditioning therapy but prior to re-infusion of stem cells (Numerator)		
Total number of patients transplanted with autologous stem cells (Denominator)		
Percentage of patients who expired after the start of conditioning therapy but prior to re-infusion of stem cells	%	%

Allogeneic	2006	2007
Number of patients who expired after the start of conditioning therapy but prior to infusion of stem cells (Numerator)		
Total number of patients transplanted with allogeneic stem cells (Denominator)		
Percentage of patients who expired after the start of conditioning therapy but prior to infusion of stem cells	%	%

6. Does the program have any protocols that involve tandem/multiple cycles of high dose chemotherapy supported by hematopoietic stem cells (tandem/multiple transplant)?

- | | | |
|---|------------------------------|-----------------------------|
| Auto/Auto | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Auto/Allo (ablative or non-myeloablative) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Multiple transplants | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

If yes, list the diagnoses for which these are performed: _____

7. Does the program perform pediatric multiple-unit cord blood transplants?
 YES NO

If yes, are these performed on an IRB approved research protocol?
 YES NO

8. Are all bone marrow/stem cell transplant patients screened for palliative care needs initially and at appropriate intervals throughout treatment and follow-up? (This question specifically refers to Palliative Care, not hospice or end-of-life care.)
 YES NO

9. Does your facility have a hospice program available to bone marrow/stem cell transplant patients, either as a direct relationship with your facility or through a referral process?

- Hospice provided through applicant facility
- Referral relationship with hospice service
- Not available

10. Does the pediatric bone marrow/stem cell transplant program have an immunologist with transplant experience available to the program?
 YES NO

11. For your allogeneic bone marrow/stem cell transplant program, is pathology available with experience in Graft versus Host Disease (GVHD)?
 YES NO Not applicable, our facility does not perform allogeneic transplants

12. Does your facility track transitions of care for patients discharged from an inpatient setting to another setting, (e.g., home, rehab facility) using a formal method for the purpose of improving the quality of care coordination and communication?
 YES NO

13. Does your facility have a formal continuous quality improvement (CQI) program in place for transplant services? *Please note: You may be required to provide documentation of your process upon request.*
 YES NO

If yes, mark your facility's CQI program components

- | | | |
|---|------------------------------|-----------------------------|
| • Written Plan that is integrated in the hospital wide QI process | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| • Specific to Bone Marrow/Stem Cell Transplant | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| • Multidisciplinary Team | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| • Quarterly meetings with minutes | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

- QI audits include indicator tracking, documentation of practice changes, and current QI projects YES NO
- Annual review of programmatic outcomes YES NO
- Transplant specific policies & procedures YES NO
- Designated person(s) appointed to review policies & procedure annually YES NO

14. Is your facility in the process of developing a transplant specific continuous quality improvement (CQI) program?

- YES NO Not Applicable, my facility has a formal CQI program in place

If no, how are transplant related issues identified, addressed, and integrated into the hospital-wide system? _____

15. Is there a formal patient selection committee that routinely meets and maintains meeting minutes specifically for the evaluation and recommendation of candidates for bone marrow/stem cell transplantation?

- YES NO

If yes, do the following personnel regularly attend these meetings?

- Program Director YES NO
- Attending Physician YES NO
- Program coordinator(s) YES NO
- Social Worker YES NO
- Consultants (if applicable) YES NO

16. Does the pediatric bone marrow/stem cell transplant program have written patient selection criteria that are applied to all pediatric transplant patients?

- YES NO

If yes, does the program have a process in place for re-evaluating patient selection criteria on an annual basis?

- YES NO

17. Does the pediatric allogeneic bone marrow/stem cell transplant program have inpatient and outpatient guidelines or protocols for graft versus host disease (GVHD) prophylaxis, identification and treatment?

- YES NO

18. Does the pediatric bone marrow/stem cell transplant program have a formal transplant specific database?

- YES NO

If no, please explain: _____

If yes,

- Is this an automated database? YES NO
- Is there limited access to data entry? YES NO
- Is this data used/reported as part of the QA/QI process? YES NO
- Who is responsible for entering data into the program?

- Provide any other information that you feel is important regarding your data base system:

PART 3: PEDIATRIC AUTOLOGOUS AND ALLOGENEIC BONE MARROW/STEM CELL TRANSPLANT TEAM

Instructions for completion of: Team Data Tables 3a & 3b

Please provide the requested information for both the Pediatric Autologous and Pediatric Allogeneic transplant programs.

1. Program Director and Transplant Physician Names
2. Provide the month/year and the title of the present appointment (example: give the month/year the physician became the program director. **IF IN THIS APPOINTED POSITION LESS THAN 2 YEARS** provide the previous 5 years of appointments/training)

NOTE: If not enough space is available on the tables for your team members, provide the information on a Word document and label attachment as “Additional Team Members”.

PART 3a: Pediatric Autologous Bone Marrow/Stem Cell Transplant Team

Please complete the table below and attach an updated CV (curriculum vitae) for all the Autologous Physicians (Label attachment by physician name)

AUTOLOGOUS Team Table

Name	Give the date and title of current appointment. IF IN THIS APPOINTED POSITION < 2 YEARS, give the last 5 years of appointments and/or training
Program Director:	
Transplant Physician(s):	

PART 3b: Pediatric Allogeneic Bone Marrow/Stem Cell Transplant Team

Please complete the table below and attach an updated CV (curriculum vitae) for all the Allogeneic Physicians (Label attachment by physician name)

ALLOGENEIC Team Table

Name	Give the date and title of current appointment. IF IN THIS APPOINTED POSITION < 2 YEARS, give the last 5 years of appointments and/or training
Program Director:	
Transplant Physician(s):	

PART 4: Section XI – Appendix B - Pediatric Patient Data Table

Please provide the information requested in the patient data table for EVERY pediatric (age 17 years or younger) who received an autologous and/or allogeneic transplant from January 1, 2004 through December 31, 2007. You must follow the instructions and use the Data Reference Codes provided. These instructions and Data Codes are included in both this Section XI Pediatric Bone Marrow/Stem Cell Transplant RFI and the Excel spreadsheet sent to you labeled as “BMT Sec X, XI Appendix B 2008 Patient Data Table”.

Instructions for completion of the Autologous/Allogeneic Patient Data Tables:

Refer to the detailed instructions on the Excel spreadsheet for proper completion of the worksheet.

The data submitted on the completed Excel spreadsheet will be used to calculate 100-day and one-year Kaplan Meier actuarial survival rates with a corresponding 95% confidence interval. The resulting calculations will be sent to your center upon completion of the review process.

- Enter all the program’s patients onto ONE spreadsheet. Enter each transplant on a separate line. Include multiple transplants, entering each transplant on a separate line, using the same ID number.
- Only include those transplants that occurred from 1/1/2004 through 12/31/2007 at your institution.
- Include all non-myeloablative transplants. Any procedure not preceded by conditioning therapy and followed by bone marrow/stem cell transplant (i.e. additional cell support for graft failure and/or donor leukocyte (DLI)) should NOT be included.
- Include all pediatric inpatient and outpatient transplants performed at your institution for patients 17 years of age and younger at time of transplant.
- Ensure the **ACCURACY** of the data prior to submission.
- **DO NOT cut and paste information into the spreadsheet as this may cause invalid data entry. Use the dropdown box when provided.**

The information is to be entered in the appropriate Microsoft Excel spreadsheet sent to you labeled as “**BMT SEC X, XI Appendix B 2008 Patient Data Table**”. DO NOT submit this patient data table in Microsoft Word or in a Text Editor format. The completed patient data table must be submitted by **secure-encrypted email** or burned to a **CD-RW** and sent to BDCT.

DATA TABLE COLUMNS:

ENTER THE INFORMATION FOR EACH TRANSPLANT ON A SEPARATE LINE WITH THE FOLLOWING INFORMATION: Use the dropdown box provided in the spreadsheet when available.

- A. Patient ID: Give the Patient an identification (ID) number. DO NOT use patient name. Each patient should be given one and only one unique patient ID number regardless of the number of times the patient was transplanted.
- B. Date of Birth: Use MM/DD/YYYY (example: 7/1/1963 or 11/15/2003)
- C. Disease: **Using the dropdown box**, enter the disease code which corresponds to the patient’s disease for which the transplant was performed. **You MUST use one of the attached disease codes. If using Other (OTH) as a disease code, provide an explanation of the diagnosis in column D.**
- D. OTH Disease: Provide the diagnosis for all the diseases listed as OTH in Column C. Only complete this field if OTH was used in column C as the disease code.
- E. Disease Stage or Remission Status: **Using the dropdown box**, enter the appropriate disease stage or remission status code which corresponds to the patient’s disease stage or remission status AT THE TIME OF TRANSPLANT. See the attached Data Reference Codes for explanation of the codes. Only use the codes with their intended diagnosis- for example, REL3+ is not a valid remission status for AML (see Data Codes below).
- F. Date of Transplant: List the Date the patient received BM/Stem Cell infusion as MM/DD/YYYY (example 3/5/2002 or 11/15/2003). If the patient received more than one course of myeloablative or non-myeloablative therapy followed by infusion of Bone Marrow/Stem Cells either as a second transplant or part of a tandem/multiple transplant protocol, enter the information on a separate line using the same patient ID number. Include dates of transplant from January 1, 2004 through December 31, 2007 only.
- G. Donor Type: **Using the dropdown box**, indicate the type/source of donor cells. This cell must be completed for all patients. For autologous patients, enter donor type “A”. Syngeneic transplants should be tabulated as matched related donor type. Donor/ Recipient pairs with one or more antigen-level mismatch at HLA- A, B, and/ or DR should be tabulated as mismatched donor type. See the attached tables for all the donor codes.
- H. Non-myeloablative Transplant:: If this transplant received by this patient represents Bone Marrow/Stem Cell infusion after non-myeloablative therapy, enter a “Y” into this box indicating Yes or “N” indicating No. This cell must be completed with a Y or N.
- I. Has the patient received a previous transplant prior to 1/1/04: Enter a “Y” into this column to indicate Yes, or “N” to indicate No. This cell must be completed with a Y or N.
- J. Date of First Relapse/Progression: If the patient has relapsed/progressed **following** transplant: Indicate the date of relapse/progression as MM/DD/YYYY (example 3/5/2002 or 11/15/2003).

- K. Date of Most Recent (documented) Follow-up: Enter the date MM/DD/YYYY (example 3/5/2002 or 11/15/2003) of the most recent **documented** follow-up with the patient. This may be left blank if the patient is deceased. **Follow-up data may be collected through actual visits to the program's BMT Physician(s) or Physician Extenders, communication with the patient's Primary Care Physician OR directly communicating with the patient via telephone, email or letter.**
- L. Survival Status: Indicate the patient's current survival status as of their most recent follow-up date. Enter "A" for Alive, "D" for Deceased. This cell must be completed with either an A or D.
- M. Date of Death: If the patient is deceased, enter the date of death as MM/DD/YYYY (example 3/5/2002 or 11/15/2003).
- N. Cause of Death: **Using the dropdown box**, enter the code which most closely corresponds to the patient's cause of death. *If using OTH as a death code, provide an explanation of death in Column O.*
- O. OTH Cause of Death: Provide the diagnosis for all the causes of death listed as OTH in column N. *Only complete this field if OTH was used in column N as the cause of death code.*
- P. Unique Center Number: For BDCT use only.

Pediatric Data Codes

**Please use the following codes when completing the patient data table.
DO NOT substitute codes or definitions.**

Disease	Subtype	Disease Code	Disease Stage or Remission Status	Disease Stage or Remission Status Code
Acute Myelogenous Leukemia		AML	Primary Induction Failure First Complete Remission Second Complete Remission Third Complete Remission ≥ Fourth Complete Remission First Relapse ≥ Second Relapse Unknown	PIF CR1 CR2 CR3 CR4+ REL1 REL2+ UNK
Acute Lymphoblastic Leukemia		ALL	Primary Induction Failure First Complete Remission Second Complete Remission Third Complete Remission ≥ Fourth Complete Remission First Relapse Second Relapse ≥ Third Relapse Unknown	PIF CR1 CR2 CR3 CR4+ REL1 REL2 REL3+ UNK
Central Nervous System		CNS		
Hodgkin Disease		HD	Primary Induction Failure First Complete Remission Second Complete Remission ≥ Third Complete Remission First Relapse Second Relapse ≥ Third Relapse Unknown	PIF CR1 CR2 CR3+ REL1 REL2 REL3+ UNK
Immune Deficiency Disorders*		IMD		
Metabolic Diseases**		MD		
Neuroblastoma		NUB		
Severe Aplastic Anemia		SAA		
Other (See instructions on previous page regarding this code)		OTH	*Must define the diagnosis in the Other column	

*Includes the following diseases: SCID, Omenn syndrome, reticular dysgenesis, bare lymphocyte syndrome, immune disorders unknown, Wiskott Aldrich syndrome, DiGeorge anomaly, Chediak-Higashi syndrome, common variable immunodeficiency, X-linked lymphoproliferative syndrome, leukocyte adhesion deficiency, neutrophil actin deficiency, chronic granulomatous disease, Kostmann agranulocytosis, CD40 Ligand deficiency, combined immunodeficiency unspecified and other immunodeficiency.

**Includes the following diseases: osteopetrosis, Lesch-Nyhan, other inherited disorders of metabolism, Hurler syndrome, Hunter syndrome, Sanfillippo, Aroteaux-Lamy, mucopolysaccharidosis, mucopolisidoses, metachromatic leukodystrophy, adrenoleukodystrophy, Krabbe disease, Neiman-Pick disease, I-cell disease, fucosidosis and mannosidosis.

**Please use the following codes when completing the patient data table.
DO NOT substitute codes or definitions.**

Donor Type	Code
Autologous	A
Allogeneic Related – Matched (6/6)	RM
Allogeneic Related - Mismatched	RMM
Allogeneic Unrelated – Matched (6/6)	UM
Allogeneic Unrelated - Mismatched	UMM
Allogeneic Cord – Related- Matched (6/6)	RCM
Allogeneic Cord – Related - Mismatched	RCMM
Allogeneic Cord – Unrelated –Matched (6/6)	UCM
Allogeneic Cord – Unrelated - Mismatched	UCMM

Survival Status	Code
Alive	A
Deceased	D

Cause of Death Codes	
Infection	INF
Hemorrhage	HEM
Pediatric respiratory distress syndrome	ARDS
Acute Graft-verses-host disease	AGVHD
Chronic Graft-verses-host disease	CGVHD
Hepatic veno-occlusive disease	HVOD
Interstitial pneumonitis	IP
Other non-infectious organ failure	ONIF
Relapse or progression of the underlying disease	REL
Other – please specify	OTH

TERMS	DEFINITION
Remission	The patient achieved a complete absence of disease and remained disease free prior to transplantation
Relapse	The patient achieved a complete remission followed by recurrence of the disease and did not achieve remission again prior to conditioning