



Registry Use Only

OMB No: 0915-0310

Sequence Number:

Expiration Date: 10/31/2022

Date Received:

Public Burden Statement: The purpose of the data collection is to fulfill the legislative mandate to establish and maintain a standardized database of allogeneic marrow and cord blood transplants performed in the United States or using a donor from the United States. The data collected also meets the C.W. Bill Young Cell Transplantation Program requirements to provide relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0310 and it is valid until 10/31/2022. This information collection is voluntary under The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109-129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111-264 (the Act) and the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114-104. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post-transplant, 0.85 hours per response when collected at 6 months post-transplant, 0.64 hours per response when collected at 1 and 2 years post-transplant, and 0.52 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: _____ - _____ - _____

YYYY MM DD

Visit:

100 day

6 months

1 year

2 years

>2 years,

Specify: _____

Survival

1. Date of actual contact with the recipient to determine medical status for this follow-up report:

____-____-____
YYYY MM DD

2. Specify the recipient's survival status at the date of last contact

- Alive – Answers to subsequent questions should reflect clinic status since the date of last report.
- Dead - Answers to subsequent questions should reflect clinic status between the date of last report and immediately prior to death. [Complete the Recipient Death Data Form 2900](#)

Primary cause of death

- ~~Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed — Go to question~~
- ~~Acute GVHD — Go to question~~
- ~~Chronic GVHD — Go to question~~
- ~~Graft rejection or failure — Go to question~~
- ~~Cytokine release syndrome — Go to question~~

Infection

- ~~Infection, organism not identified — Go to question~~
- ~~Bacterial infection — Go to question~~
- ~~Fungal infection — Go to question~~
- ~~Viral infection — Go to question~~
- ~~COVID-19 (SARS-CoV-2) — Go to question~~
- ~~Protozoal infection — Go to question~~
- ~~Other infection — Go to question~~

Pulmonary

- ~~Idiopathic pneumonia syndrome (IPS) — Go to question 5~~
- ~~Pneumonitis due to Cytomegalovirus (CMV) — Go to question 5~~
- ~~Pneumonitis due to other virus — Go to question 5~~
- ~~Other pulmonary syndrome (excluding pulmonary hemorrhage) — Go to question~~
- ~~Diffuse alveolar damage (without hemorrhage) — Go to question~~
- ~~Acute respiratory distress syndrome (ARDS) (other than IPS) — Go to question~~

Organ failure (not due to GVHD or infection)

- ~~_____ Liver failure (not VOD) — Go to question~~
- ~~_____ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) — Go to question~~
- ~~_____ Cardiac failure — Go to question~~
- ~~_____ Pulmonary failure — Go to question~~
- ~~_____ Central nervous system (CNS) failure — Go to question~~
- ~~_____ Renal failure — Go to question~~
- ~~_____ Gastrointestinal (GI) failure (not liver) — Go to question~~
- ~~_____ Multiple organ failure — Go to question~~
- ~~_____ Other organ failure — Go to question~~

Malignancy

- ~~_____ New malignancy (post-HCT or post-cellular therapy) — Go to question~~
- ~~_____ Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed) — Go to question~~

Hemorrhage

- ~~_____ Pulmonary hemorrhage — Go to question~~
- ~~_____ Diffuse alveolar hemorrhage (DAH) — Go to question~~
- ~~_____ Intracranial hemorrhage — Go to question~~
- ~~_____ Gastrointestinal hemorrhage — Go to question~~
- ~~_____ Hemorrhagic cystitis — Go to question~~
- ~~_____ Other hemorrhage — Go to question~~

Vascular

- ~~_____ Thromboembolic — Go to question~~
- ~~_____ Disseminated intravascular coagulation (DIC) — Go to question~~
- ~~_____ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic-Uremic Syndrome (HUS)) — Go to question~~
- ~~_____ Other vascular — Go to question~~

Other

- ~~_____ Accidental death — Go to question~~
- ~~_____ Suicide — Go to question~~
- ~~_____ Other cause — Go to question~~

Specify: _____

Contributing cause of death (check all that apply)

- Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed — **Go to question 3.**
- Acute GVHD — **Go to question 3.**
- Chronic GVHD — **Go to question 3.**
- Graft rejection or failure — **Go to question 3.**
- Cytokine release syndrome — **Go to question 3.**

Infection

- Infection, organism not identified — **Go to question 3.**
- Bacterial infection — **Go to question 3.**
- Fungal infection — **Go to question 3.**
- Viral infection — **Go to question 3.**
- COVID-19 (SARS-CoV-2) — **Go to question 3.**
- Protozoal infection — **Go to question 3.**
- Other infection — **Go to question**

Pulmonary

- Idiopathic pneumonia syndrome (IPS) — **Go to question 3.**
- Pneumonitis due to Cytomegalovirus (CMV) — **Go to question 3.**
- Pneumonitis due to other virus — **Go to question 3.**
- Other pulmonary syndrome (excluding pulmonary hemorrhage) — **Go to question**
- Diffuse alveolar damage (without hemorrhage) — **Go to question 3.**
- Acute respiratory distress syndrome (ARDS) (other than IPS) — **Go to question 3.**

Organ failure (not due to GVHD or infection)

- Liver failure (not VOD) — **Go to question 3.**
- Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) — **Go to question 3.**
- Cardiac failure — **Go to question 3.**
- Pulmonary failure — **Go to question 3.**
- Central nervous system (CNS) failure — **Go to question 3.**
- Renal failure — **Go to question 3.**
- Gastrointestinal (GI) failure (not liver) — **Go to question 3.**
- Multiple organ failure — **Go to question**
- Other organ failure — **Go to question**

Malignancy

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- II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*
- III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*
- IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL*
- Not applicable (*acute GVHD present but cannot be graded*)

List the stage for each organ at diagnosis of acute GVHD:

19. Skin

- Stage 0 – *no rash, no rash attributable to acute GVHD*
- Stage 1 – *maculopapular rash, < 25% of body surface*
- Stage 2 – *maculopapular rash, 25–50% of body surface*
- Stage 3 – *generalized erythroderma, > 50% of body surface*
- Stage 4 – *generalized erythroderma with bullae formation and/or desquamation*

20. Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

- Stage 0 – *no diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*
- Stage 1 – *diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)*
- Stage 2 – *diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- Stage 4 – *severe abdominal pain, with or without ileus, and/or grossly bloody stool*

21. Upper intestinal tract

- Stage 0 – *no persistent nausea or vomiting*
- Stage 1 – *persistent nausea or vomiting*

22. Liver

- Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- Stage 1 – *bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- Stage 2 – *bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- Stage 3 – *bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- Stage 4 – *bilirubin > 15.0 mg/dL (> 256 µmol/L)*

23. Other site(s) involved with acute GVHD

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- Yes – **Go to question 24.**
- No – **Go to question 25.**

24. Specify other site(s): _____

Specify the maximum overall grade and organ staging of acute GVHD since the date of last report

25. Maximum overall grade of acute GVHD

- I - *Rash on ≤ 50% of skin, no liver or gut involvement*
- II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*
- III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*
- IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL*
- Not applicable (*acute GVHD present but cannot be graded*)

26. First date of maximum overall grade of acute GVHD: _____ - _____ - _____

27. Skin

- Stage 0 – *no rash, no rash attributable to acute GVHD*
- Stage 1 – *maculopapular rash, < 25% of body surface*
- Stage 2 – *maculopapular rash, 25–50% of body surface*
- Stage 3 – *generalized erythroderma, > 50% of body surface*
- Stage 4 – *generalized erythroderma with bullae formation and/or desquamation*

28. Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

- Stage 0 – *no diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*
- Stage 1 – *diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)*
- Stage 2 – *diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- Stage 4 – *severe abdominal pain, with or without ileus, and/or grossly bloody stool*

29. Upper intestinal tract

- Stage 0 – *no persistent nausea or vomiting*
- Stage 1 – *persistent nausea or vomiting*

30. Liver

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YYYY MM DD

38. Specify if chronic GVHD was limited or extensive

- Limited - *localized skin involvement and/or liver dysfunction*
- Extensive – *one or more of the following:*
 - *generalized skin involvement; or,*
 - *liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,*
 - *involvement of eye: Schirmer's test with < 5 mm wetting; or*
 - *involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or*
 - *involvement of any other target organ*

39. Is the recipient still taking systemic steroids? (*Do not report steroids for adrenal insufficiency, or steroid dose ≤10 mg/day for adults, <0.1 mg/kg/day for children*)

- Yes
- No
- Not applicable
- Unknown

40. Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

- Yes
- No
- Not applicable
- Unknown

Liver Toxicity Prophylaxis

41. Was specific therapy used to prevent liver toxicity?

- Yes – **Go to question 42.**
- No – **Go to question 44.**

42. Specify therapy (*check all that apply*)

- Defibrotide – **Go to question 44.**
- Heparin – **Go to question 44**
- Enoxaparin (Lovenox) – **Go to question 44**
- N-acetylcysteine – **Go to question 44.**
- Tissue plasminogen activator (TPA) – **Go to question 44.**

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61. Was the new malignancy donor / cell product derived?
- Yes – **Go to question 62.**
 - No – **Go to question 62.**
 - Not done – **Go to question 63.**
62. Was documentation submitted to the CIBMTR? (*e.g. cell origin evaluation (VNTR, cytogenetics, FISH)*)
- Yes
 - No

Chimerism Studies (Cord Blood Units, Beta Thalassemia, and Sickle Cell Disease Only)

This section relates to chimerism studies from allogeneic **infusions** using cord blood units or for recipients whose primary disease is beta thalassemia or sickle cell disease. If this was an autologous **infusion**, or an allogeneic **infusion** using a bone marrow or PBSC product, or a different primary disease, continue to disease assessment.

63. Were chimerism studies performed since the date of last report?
- Yes – **Go to question 64.**
 - No – **Go to question 82.**
64. Was documentation submitted to the CIBMTR? (*e.g. chimerism laboratory reports*)
- Yes
 - No
65. Were chimerism studies assessed for more than one donor / multiple donors?
- Yes
 - No

Provide date(s), method(s) and other information for all chimerism studies performed since the date of last report.

Copy and complete questions 66. – 81. for multiple chimerism studies.

NMDP donor ID: _____

66. Global Registration Identifiers for Donors (GRID): _____

67. NMDP cord blood unit ID: _____

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68. Registry donor ID: _____

69. Non-NMDP cord blood unit ID: _____

70. Donor date of birth: _____ - OR - Donor age: _____

YYYY MM DD

Months

Years

71. Donor sex

- Male
- Female

72. Date sample collected: _____

YYYY MM DD

73. Method

- Karyotyping for XX/XY – **Go to question 75.**
- Fluorescent in situ hybridization (FISH) for XX/XY – **Go to question 75.**
- Restriction fragment-length polymorphisms (RFLP) – **Go to question 75.**
- VNTR or STR, micro or mini satellite (also include AFLP) – **Go to question 75.**
- Other – **Go to question 74.**

74. Specify: _____

75. Cell source

- Bone marrow
- Peripheral blood

76. Cell type

- Unsorted / whole – **Go to question 78.**
- Red blood cells – **Go to question 80.**
- Hematopoietic progenitor cells (e.g. CD34+ cells) – **Go to question 80.**
- Total mononuclear cells (e.g. lymphs & monos) – **Go to question 80.**
- T-cells (includes CD3+, CD4+, and/or CD8+) – **Go to question 80.**
- B-cells (includes CD19+ or CD20+) – **Go to question 80.**
- Granulocytes (includes CD33+ myeloid cells) – **Go to question 80.**
- NK cells (e.g. CD56+) – **Go to question 80.**

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Post-Infusion Therapy

In questions 105.-109., report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

105. Was therapy given since the date of the last report for reasons other than relapsed, persistent, or progressive disease? *(Include any maintenance and consolidation therapy.)*

- Yes - **Go to question 106.**
- No - **Go to question 114.**

106. Specify therapy *(check all that apply)*

- Blinded randomized trial - **Go to question 114.**
- Cellular therapy - **Go to question 114.**
- Radiation - **Go to question 114.**
- Systemic therapy - **Go to question 107.**
- Other therapy - **Go to question 109.**

107. Specify systemic therapy *(check all that apply)*

- Alemtuzumab (Campath)
- Azacytidine (Vidaza)
- Blinatumomab
- Bortezomib (Velcade)
- Bosutinib
- Brentuximab vendotin**
- Carfilzomib
- Chemotherapy**
- Daratumumab (Darzalex)**
- Dasatinib (Sprycel)
- Decitabine (Dacogen)
- Gemtuzumab (Mylotarg, anti-CD33)
- Gilteritinib
- Ibrutinib
- Imatinib mesylate (Gleevec)
- Ixazomib
- Lenalidomide (Revlimid)

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- Other therapy - **Go to question 124.**

122. Specify systemic therapy (check all that apply)

- Alemtuzumab (Campath)
- Azacytidine (Vidaza)
- Blinatumomab
- Bortezomib (Velcade)
- Bosutinib
- Carfilzomib
- Chemotherapy
- Daratumumab (Darzalex)**
- Dasatinib (Sprycel)
- Decitabine (Dacogen)
- Gemtuzumab (Mylotarg, anti-CD33)
- Gilteritinib
- Ibrutinib
- Imatinib mesylate (Gleevec)
- Ixazomib
- Lenalidomide (Revlimid)
- Lestaurtinib
- Midostaurin
- Nilotinib (AMN107, Tasigna)
- Nivolumab
- Pembrolizumab
- Pomalidomide
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Venetoclax**
- Other systemic therapy- **Go to question 123.**

123. Specify other systemic therapy: _____

