CME Disclosure

• We have no financial relationships to disclose
Objectives

• Understand changes on Form 2400 (pre-TED) that impact Forms Due
• Understand changes on Form 2000 (Baseline)
• Utilize tips for reporting on Forms 2400 and 2000
  – Donor ID
  – Product Manipulation
  – Drug regimen and drug doses
  – Co-morbidities
Changes to Forms Due

• Pre-TED is now required for every transplant
  – TED or CRF track
  – First or subsequent transplant

• Why?
  – Many fields were removed from the F2000
  – Data is required for TCSA
  – Enables CIBMTR to perform more studies on patients on TED track
F24000 changes impacting Forms Due

• Donor information has been updated
  – Multiple
    • Captures IDs, donor type, product type, sex, and DOB
  – Helps determine correct forms due

• CIBMTR continuously reviews cases to make sure critical data are reported, so forms may be added later
Forms Due

• Answers to questions on the 2400 determine which other forms come due
  – CRF vs. TED track
  – Appropriate disease forms when assigned to CRFs
Recipient Demographics (Q3-4)

• New option values added to Ethnicity and Race on the pre-TED
  – Not applicable (not a resident of the USA) – only for Ethnicity
  – Not reported – only for Race
  – Unknown
  – Avoid overriding these questions

• Ethnicity has been removed from Form 2000
Recipient Demographics (Q5)

• Zip or postal code for place of recipient’s residence added to pre-TED
  – Important variable for studies on patients on the TED track
  – Removed from Form 2000
Clinical Trials on pre-TED (Q6-10)

• Additional options for Study Sponsor have been added
  – USIDNET
  – COG
• Ensures the correct forms are due
• Do not report any studies that do not use CIBMTR data
  – Example: most studies sponsored by pharmaceutical companies
• Not necessary to report 10-CBA
Transplant History (Q12-28)

• Detailed information on prior transplants added to pre-TED
  – Source for all prior HCTs
  – Source for last HCT
  – Reason for current HCT

• Was this donor used for any prior HCTs added to pre-TED
  – For the same recipient
  – Determines how many 2005 forms are made due

• HCT history section removed from Form 2000
Donor Information on pre-TED (Q29-45)

• Donor Information
  – More donor options have been added
    • Autologous cord blood unit
    • Related cord blood unit

To report more than one donor, copy questions 31-62 and complete for each donor.

31. Specify donor:
- □ Autologous - Go to question 48
- □ Autologous cord blood unit - Go to question 35
- □ NMDP unrelated cord blood unit - Go to question 32
- □ NMDP unrelated donor - Go to question 33
- □ Related donor - Go to question 40
- □ Related cord blood unit - Go to question 35
- □ Non-NMDP unrelated donor - Go to question 34
- □ Non-NMDP unrelated cord blood unit - Go to question 35
Donor/Cord Blood Unit IDs on Pre-TED (Q32-45)

• IDs need to match across all forms
• ALWAYS need an ID for cords and NMDP products. Only related PBSC, marrow and autos would not have an id
  – NMDP IDs only have numbers
• Auto cord
  – If a product was frozen and stored, it has an ID
  – Used to match outcomes back to bank records
Reporting Donor IDs on Pre-TED

32. NMDP cord blood unit ID: ____________ - Go to question 46
33. NMDP donor ID: ____________ - Go to question 48
34. Non-NMDP unrelated donor ID: (not applicable for related donors) ____________ - Go to question 38
35. Non-NMDP cord blood unit ID: (Include related and autologous CBUs) ____________
36. Is the CBU ID also the ISBT DIN number?
   □ Yes
   □ No → 37. Specify the ISBT DIN number: ______________________________
38. Registry or UCB Bank ID: ____________ - If 'Other registry' go to 39, otherwise go to question 41
39. Specify other Registry or UCB Bank: ______________________________ - Go to question 41
40. Specify the related donor type:
   □ Syngeneic (monozygotic twin)
   □ HLA-identical sibling (may include non-monozygotic twin)
   □ HLA-matched other relative
   □ HLA-mismatched relative
41. Date of birth: (donor/infant)
   □ Known → 42. Date of birth: (donor/infant): ______/_____/______
   □ Unknown
42. Date of birth: (donor/infant): ______/_____/______
43. Age: (donor/infant)
   □ Known → 44. Age: (donor/infant) ____
   □ Unknown
44. Age: (donor/infant) ____
   □ Months (use only if less than 1 year old)
   □ Years
45. Sex: (donor/infant) □ Male □ Female
Registry or UCB Bank ID (Q38-39)

- Many large registries still have 2 codes
- CRIR being retired – Use USA1 or U1CB
- New Cord Blood Banks added:
  - SLCBB
  - Viacord
  - Cord Blood Registry
- Other, specify option added to improve validation – USE SPARINGLY
- TIP: Search BMDW or 2006 (PDF-RF)
Reporting Product Mobilization on Pre-TED (Q51-62)

• Product mobilization questions have been added for Autologous donor

• Number of Form 2005s due depends on
  – Q30 “Number of donors”
  – Q60 “Was this donor used for any prior HCTs”

• Number of Form 2006s due depends on
  – Q51 “Number of products infused from this donor”
  – Q53 “Number of mobilization events”
Consent (Q63-70)

- Consent to Research and Consent to Specimen repository questions added to pre-TED
  - Confirm the consent to research on the pre-TED and Form 2000 (R1-R3)
- Permission to contact recipient for future research
  - CIBMTR can contact patient to tell about study
  - Study would involve the patient directly (e.g. completing survey)
- Donor consent to specimen repository (related donors only)
Product processing / Manipulation (Q71-89)

- Product manipulation questions have been expanded
  - Tumor purging removed – report on 2006
  - Manipulation options were updated to meet FACT definitions
- Jenni Bloomquist will provide more information during Form 2006 presentation
Tips on reporting Co-morbid Conditions on pre-TED (Q95)

• Report invasive fungal infections
  – invasive aspergillosis
  – zygomycosis and other molds
• Do not report non-invasive fungal infections
  – nail fungus
• Infection details are still reported on the 2000 form
Co-morbid Conditions on pre-TED (Q96-132)

• Co-morbidity is NOT the same as past medical history.

• Intent is to identify pre-existing conditions that may have an effect on outcome of HCT
  – Used in TCSA to account for differences in survival rates for sicker patients
Tips on reporting co-morbidity on Pre-TED

• Should Report - Conditions being treated at the time of pre-HCT evaluation, or have affected the patient’s medical history or may cause complications post HCT

• Should Not Report - Conditions that have been resolved and/or that would not pose a concern during or after HCT
Reporting Prior Malignancies on Pre-TED (Q113-154)

• Co-morbid conditions on pre-TED
  – Solid tumor includes options to indicate the type of solid tumor
  – History of malignancies other than Primary disease added
    • Capture hematologic malignancies & other solid tumors (e.g., non-melanoma skin cancers) not captured under solid tumor
• Removed from Form 2000
Tips on reporting co-morbidity on Pre-TED

• Do not report specific lab values
  – Not usually relevant or reportable
    • Ejection Fraction >50%

• Generic descriptions are not enough information to determine significance
  – Obesity
  – Elevated liver function tests
Tips on reporting co-morbidity on Pre-TED

• Some conditions may be relevant for some patients and not others, depending on the primary disease
  – Amyloidosis
    • Not reported for myeloma patients
    • Reported for non myeloma patients

• Some conditions are not clinically significant; if severe enough to cause other problems, report those problems
  – Rheumatic fever can cause heart valve problems
Important questions to ask…

• Is the co-morbidity associated with the primary disease?
• Is the patient receiving any medical intervention for the condition?
Resources for reporting co-morbidities

- For more information on reporting co-morbidities
  - [Dr. Pasquini gave presentation on co-morbidities at 2011 CRP/DM conference](#)
  - [See appendix U of the Pre-TED manual](#)
  - When in doubt, ask your CRC
Preparative Regimen on Pre-TED (Q157-315)

• New questions have been added
  – Height and Weight at initiation of preparative regimen
    • Adjusted body weight only reported on 2000
    • If your center does not report Adjusted/Dosing weight, provide the actual weight
  – If height and/or weight are unknown, do not enter the units
Preparative Regimen (contd.)

• Date preparative regimen began and dates individual agents were started
• Prescribed radiation field
• TBI fractionation
Preparative Regimen (contd.)

• Drugs updated to generic names on both pre-TED and Form 2000
  – Campath → Alemtuzumab (Campath)
  – BCNU (Carmustine) → Carmustine (BCNU)

• Drugs have been added
  – Treosulfan
  – Tyrosine kinase inhibitors expanded
    • Dasatinib (Sprycel), Nilotinib

• Regimen type removed from 2000
Tips for reporting regimen doses on pre-TED

• Report the total prescribed dose per body weight (mg dose/kg) or body surface area (mg dose/m²) to be given
  – As indicated in the transplant protocol or standard of care
  – Note the administration frequency (i.e. daily dose, every six hours, etc.) when determining the total prescribed dose

• Should NOT report the total dose that was actually infused
  – Prescribed dose should be comparable to dose reported on 2000
  – Dose changed due to pharmacokinetics (PK)
## CIBMTR Classification of Preparative Drug Doses

<table>
<thead>
<tr>
<th>Agent</th>
<th>Myeloablative Dose</th>
<th>RIC/NMA Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBI</td>
<td>&gt; 500 cGy (single dose) or &gt; 800 cGy (fractionated)</td>
<td>&lt; 500 cGy (single dose) or &lt; 800 cGy (fractionated)</td>
</tr>
<tr>
<td>Busulfan</td>
<td>&gt; 7.2 mg/kg IV or &gt; 9.0 mg/kg PO</td>
<td>&lt; 7.2 mg/kg IV or &lt; 9.0 mg/kg PO</td>
</tr>
<tr>
<td>Busulfan</td>
<td>&gt; 300 mg/m2 IV or &gt; 375 mg/m2 PO</td>
<td>&lt; 300 mg/m2 IV or &lt; 375 mg/m2 PO</td>
</tr>
<tr>
<td>Melphalan</td>
<td>&gt; 150 mg/m2</td>
<td>&lt; 150 mg/m2</td>
</tr>
<tr>
<td>Thiotepa</td>
<td>&gt; 10 mg/kg</td>
<td>&lt; 10 mg/kg</td>
</tr>
<tr>
<td>Treosulfan</td>
<td>&gt; 30,000 mg/m2 (or 30 g/m2)</td>
<td>&lt; 30,000 mg/m2 (or 30 g/m2)</td>
</tr>
</tbody>
</table>
### Reduced Intensity Preparative Regimens

<table>
<thead>
<tr>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATG + Cyclophosphamide</td>
</tr>
<tr>
<td>Carmustine + Etoposide + Cytarabine + Melphalan (BEAM)</td>
</tr>
<tr>
<td>Fludarabine + ARA-C</td>
</tr>
<tr>
<td>Cyclophosphamide + Etoposide</td>
</tr>
</tbody>
</table>
CIBMTR Classification of Non-Myeloablative Preparative Regimens

<table>
<thead>
<tr>
<th>Non-Myeloablative Preparative Regimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fludarabine + TBI &lt; 200 cGy</td>
</tr>
<tr>
<td>TBI &lt; 200 cGy</td>
</tr>
<tr>
<td>Fludarabine + Cyclophosphamide</td>
</tr>
<tr>
<td>Fludarabine + Cytarabine (ARA-C)</td>
</tr>
</tbody>
</table>
Reporting dose when pharmacokinetics are performed

- If test dose is given 1 or more days before first therapeutic dose is given
  - On the pre-TED, report the total prescribed dose per protocol without the test dose included
  - On the 2000, the test dose should not be included in the total dose

- If the first dose of the preparative regimen is used to determine PK
  - On the pre-TED, report the total prescribed dose per protocol
  - On the 2000, the test dose should be included in the total dose
Tips for reporting on Pre-TED

• Treosulfan
  – Patient receives dose in grams, not mg
  – On the pre-TED the units are mg/kg or mg/m²
    • 42 g/m² = 42,000 mg/m²
  – On the Form 2000 the units are mg
    • Treosulfan should be reported in the “Other Drug, specify” field

• Janet Brunner will provide more information during Conditioning Drugs presentation
  – 2:45 pm – 3:30 pm on 02/26/2014
Disease Information on Pre-TED

• Primary Disease for HCT
  – Diseases have been updated to match the W.H.O classification
  – Cytogenetics studies added
  – Molecular Markers
  – Status at transplantation – Date of most recent relapse

• Dr. Tomblyn gave presentation on Molecular Markers at 2013 Tandem
Disease Information on Pre-TED

- New disease options have been added
  - Dyskeratosis congenita – SAA
  - POEMS syndrome – Multiple Myeloma
  - Sarcomas have been expanded under Solid tumor
- Some of the disease options have been moved
  - Breast cancer - Solid tumor
  - PNH – Inherited abnormalities of erythrocyte differentiation or function
- Other disease – use rarely
  - Neuroblastoma is under Solid tumor
Tips of reporting on pre-TED

357 What was the primary disease for which the HCT was performed?
- Acute myelogenous leukemia (AML or ANLL) (10)
- Acute lymphoblastic leukemia (ALL) (20)
- Other acute leukemia (80)
- Chronic myelogenous leukemia (CML) (40)
- Myelodysplastic (MDS) / myeloproliferative (MPN) diseases (50) (Please classify all preleukemias)
- Other leukemia (30) (includes CLL)
- Hodgkin lymphoma (150)
- Non-Hodgkin lymphoma (100)
- Multiple myeloma / plasma cell disorder (PCD) (170)
- Solid tumors (200)
- Severe aplastic anemia (300) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease)
- Inherited abnormalities of erythrocyte differentiation or function (310)
- Disorders of the immune system (400)
- Inherited abnormalities of platelets (500)
- Inherited disorders of metabolism (520)
- Histiocytic disorders (570)
- Autoimmune diseases (600)
- Other disease (900)
Tips of reporting on pre-TED

Other Disease

645 Specify other disease:
Disease Information (contd.)

• MDS
  – Lab studies at diagnosis and prior to preparative regimen added
  – Used to calculate disease risk for TCSA
• Autoimmune disorders
  – Primary reason for transplant was removed from pre-TED
• Disease section removed from Form 2000
Tips on reporting Disease on Pre-TED

• Examples of disease transformation
  – MDS transformed to AML

• Specific disease under AML:
  – AML,NOS
  – AML with multilineage dysplasia (prior versions)
  – AML with myelodysplasia – related changes (R4)

• Specific disease under MDS
  – AML, NOS (at transplant – prior versions)
  – Transformed to AML (R4)
Tips on reporting on pre-TED

| CIBMTR Form 2100 revision 4 (page 20 of 45), Last Updated October, 2013. |
| CIBMTR Recipient ID: __________________________ |

| CIBMTR Center Number: ____________ |

525. Did the recipient progress or transform to a different MDS/MPN subtype between diagnosis and the start of the pretransplant regimen?
- [ ] Yes
- [ ] No

Specify the date of the most recent transformation:
- [ ] ☐ YMM
- [ ] ☐ MM
- [ ] ☐ DD

527. Specify the MDS/MPN classification after transformation:
- Refractory cytopenia with unilineage dysplasia (RCUD) (51)
- Refractory anemia with ringed sideroblasts (RARS) (55)
- Refractory anemia with excess blasts-1 (RAEB-1) (61)
- Refractory anemia with excess blasts-2 (RAEB-2) (62)
- Refractory cytopenia with multilineage dysplasia (RCMD) (64)
- Childhood myelodysplastic syndrome (Refractory cytopenia of childhood (RCC)) (66)
- Myelodysplastic syndrome with isolated del(5q) (5q- syndrome) (68)
- Myelodysplastic syndrome (MDS), unclassifiable (50)
- Chronic neutrophilic leukemia (165)
- Chronic eosinophilic leukemia, NOS (166)
- Essential thrombocythemia (Includes primary thrombocytosis, idiopathic thrombocythemia, hemorrhagic thrombocythemia) (59)
Tips on reporting Disease on Pre-TED

• CLL transformed to NHL (Richter syndrome)
  – Primary disease - NHL
  – Specific disease under NHL:
    • Diffuse, large B-cell lymphoma
  – Specific disease under CLL:
    • Chronic lymphocytic leukemia (CLL), NOS
    • Chronic lymphocytic leukemia (CLL), B-cell/small lymphocytic lymphoma (SLL)
Tips on reporting on Pre-TED

• Status at transplant
  – Confirm the status reported on the Pre-HCT disease form matches the disease status on Pre-TED
  – Needed to calculate the disease status for CVDR
HLA Information on pre-TED (R1, R2 and R3)

- HLA information has been removed from Pre-TED (R4)
- HLA mismatches reported on previously submitted Pre-TEDs – will not be updated
  - CIBMTR will be adding Form 2005 to collect HLA data (if needed)
Resources for HLA reporting

• Additional training material is available at
  • HLA Reporting - Form 2005

• For any HLA questions contact Maria Brown at mbrown2@nmdp.org
  • Include HLA report
Tips for reporting GVHD Prophylaxis on Pre-TED

• GVHD Prophylaxis
  – Required for all Allogeneic transplants (except Syngeneic)
  – If on CRF track, needs to match what was reported on Form 2100 (CRF patients)
Changes to Form 2000

• Option value has been changed under Infection section
  – Not done → Not tested

• Some of the questions removed
  – Gender/Sex
  – Date of birth
  – Karnofsky/Lansky scale and score
Tips for reporting disease on Form 2000 (R1, R2 and R3)

• Specific disease reported needs to match with the pre-TED
• Disease section removed from Form 2000 (R4)
eLearning

• Pre-TED Training modules are available on the CIBMTR Learning Management System
  – Pre-TED Module 1
  – Pre-TED Module 2