To: Transplant Center Medical Directors and Data Managers

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RE: Preparative Regimen Data Reporting (Prescribed v Actual Dosing)

The CIBMTR has recently been working with some transplant centers on a prospective study and identified a potential misunderstanding regarding how to report preparative regimen data on the Pre-TED (2400) form. While working cooperatively with the European Group for Blood and Marrow Transplantation (EBMT), they have also observed the same issue with data being reported on the MED-A form.

The intent of the preparative regimen section on the Pre-TED (2400)/MED-A form is to capture accurate information regarding drugs used and dosage crucial to the evaluation of transplant regimens. Centers should report the total prescribed cumulative dose per body weight (dose/kg) or surface area (dose/m²) to be given as indicated in the transplant protocol or standard of care, not the administration frequency dose (i.e. daily dose, every six hours dose, etc.). Centers should NOT report the total dose that was actually infused. The form is designed to capture the protocol regimen only.

If the units documented in the medical record are different from the available options on the form, please convert the dose and tick the appropriate unit. If this is not possible, e.g. campath or pediatric doses of busulfan may only be listed in milligrams (mg), centers reporting to CIBMTR should leave the unit field blank and attach a copy of the source document to the Pre-TED using the Log of Appended Documents (Form 2800). Centers reporting to EBMT, write on the margin the name of the units used.

Examples of correct reporting on the Pre-TED (2400)/MED-A form:

1. Patient’s transplant protocol: IV busulfan at 0.8 mg/kg every 6 hours for 16 doses. The total prescribed cumulative dose would = 12.8 mg/kg.
2. Patient’s transplant protocol: fludarabine at 75 mg/m² daily for 2 days. The total prescribed cumulative dose would = 150 mg/m².
3. Patient’s transplant protocol: total body irradiation (TBI) at 2 Gy twice a day for 3 days. The total prescribed cumulative dose would = 12 Gy.
If the dose includes a decimal, please round down to the nearest whole number if <0.5, round up if ≥0.5.

**CIBMTR Only:**
If the patient is selected for CIBMTR comprehensive Report Forms (cRF), the actual total dose received is reported on the Recipient Baseline Data (2000) form. If the total dose is adjusted for any reason, as a result of test dosing or dose modifications, that information will be captured on the Baseline Form. See the attached document for a case study example.

Please feel free to contact your CIBMTR liaison if you have additional questions about preparative regimen reporting.
Case Study Example:

A patient is assigned to the standard of care regimen Cyclophosphamide and TBI. The regimen calls for cyclophosphamide at 60 mg/kg on each of two days, and TBI at 200 cGy in 6 fractions over 3 days. The patient has an actual body weight of 96 kg, an ideal body weight of 78 kg, and is dosed based upon a weight of 82 kg (dose adjusted weight).

For the Pre-TED (2400)/MED-A form, the following information should be provided:

TBI total prescribed dose = 1200 cGy

67. 1 □ yes 2 □ no cyclophosphamide → 68. 120

Cyclophosphamide total prescribed dose = 120 mg/kg.

67. 1 □ yes 2 □ no cyclophosphamide → 68. 120

For the CIBMTR Recipient Baseline Data (2000) form, the following information should be provided:

TBI total dose given = 1200 cGy, radiation fractionated, 200 cGy per fraction, 3 days, 6 total fractions.

191. Was irradiation performed as part of the pre-HSCT preparative regimen?

1 □ yes
2 □ no

192. What was the radiation field?

1 □ total body
2 □ total body by tomotherapy

193. Total dose: 1200 cGy

194. Date started: 2004-03-09

195. Was the radiation fractionated?

1 □ yes
2 □ no

196. Dose per fraction: 200 cGy

197. Number of days: 3

198. Total number of fractions: 6

Cyclophosphamide total dose (dose adjusted) given = 9840 mg. (120 mg/kg x 82 kg = 9840 mg total)

283. Cyclophosphamide

1 □ yes 284. 9840 mg

2 □ no