Form 2006: HSCT Infusion

The form 2006 (INF) is designed to capture product and infusion specific information for all products given to a recipient as part of a transplant. This includes cells given prior to the transplant for reasons other than engraftment. In addition to its research purpose, this information is used for quality assurance measures, both by the NMDP and the Cord Blood Banks. CIBMTR has prepared the following guidance to aid you in determining how to report the data for a variety of scenarios.

FAQ:

What is the difference between questions 14 and 191?

The intent of question 14 is to cover what happens during collection or processing before frozen or shipped. What we really want to know is what anticoagulants were used during the collection, either given to the donor or added to the product before shipping. The intent of question 191 is to capture what your center added, either after the product was thawed or during manipulation. If you received a fresh product, add something, and then cryopreserved it, you would report NO to question 14 and yes to question 191.

Our facility functions as the collection center as well as the transplant center. What information should be provided about the collection process?

Question 1-19 are the only ones that refer specifically to the collection process. All other questions on the form should be answered from the perspective of the transplant center group. If your collection and transplant facility are the same, then the answer is NO to both Q20 and Q31. If your sites are not the same, Q20 would be YES, and Q31 should be answered as appropriate.

We saved some bags from a previous infusion which were cryopreserved and are now transplanting them. How does this impact the response for Q31?

If the collection facility and the transplant center are the same, this would be answered NO, and Q32 would be YES. Essentially this means, if the product was shipped fresh from elsewhere, received, and then frozen (some or all of it) before it was infused, then the answer to Q31 is YES.

If one of the bags of a product is contaminated, but not the others, how does that get reported?

If one of the bags of a product is contaminated, all of that product is considered contaminated for the purposes of reporting to the CIBMTR on Form 2006. If there are multiple products involved in the infusion, but only one is contaminated, then only report the infection on the 2006 for the product that was contaminated **(since there would a separate F2006 for the other product that was infused).**

Our center has a protocol where NK Cells from a cord blood unit are infused during the preparative regimen. These cells are not intended for engraftment. Should these be reported?

Yes. If the infusion was given prior to the actual transplant (dated based upon the date of infusion of hematopoietic cells intended for engraftment), the cells need to be reported as a product on the Form 2400 (Pre-TED) and on a separate Form 2006. If the cells were infused after the transplant, they should be reported as a DCI on the appropriate follow-up form. Reporting the NK (or other cells given pre HCT but not for engraftment) on a 2006 is the only mechanism in place to collect these data, as well as to get the quality assurance data back to the Cord Blood Banks on their units. Question 184 is intended to address this scenario. If the cells are infused on a different date from the HCT product intended to produce engraftment, indicate NO in question 184 and provide the date that the additional cells were given. The "Date of this HSCT" for this form 2006 should be the date of the actual transplant of hematopoietic cells intended to produce engraftment.

Example:
3 units infused, one not intended for engraftment (NK Cells). A 2006 is required for each unit.

NK Cells from a CBU ("1") infused 9/15/2009
HSCT Date = 9/20/09
Q183 = YES
Q184 = NO
Q185 = 9/15/2009

CBU "2" infused 9/20/2009
HSCT Date = 9/20/09
Q183 = YES
Q184 = YES

CBU "3" infused 9/20/2009
HSCT Date = 9/20/09
Q183 = YES
Q184 = YES

How do I distinguish between single and multiple products?

The CIBMTR considers a product to be all bags collected from the same mobilization event. If an additional agent is administered to the donor/patient and then more cells are collected, this becomes an additional mobilization and thus a new product. One product can have multiple collections, usually collected over different days. The Form 2006 (INF) should be completed for each *product*, not each collection or bag. For single products with multiple bags, the questions on the 2006 should all be answered on the whole product (all of the bags combined). If the bags were each tested or manipulated separately, the responses on the 2006 should reflect the combined values. For the product analysis section, this means adding the totals of all of the bags (averaging viability). For the manipulation section, this means reporting all manipulations that were done to any part of the product. If different bags were manipulated differently, question 45 should indicate that a PORTION of the product was manipulated. For cases where there was a multiple bag product that is infused in parts over multiple transplants, a 2006 should be submitted on that product for each transplant. The first 2006 (submitted for the first transplant) should include only the cells that are thawed for the first transplant. Q33 is answered NO, and Q36 indicates how many bags were thawed. The second 2006 (submitted for the second transplant) should include only the cells that are thawed for the second transplant. If this is the entirety of the remainder, Q33 will indicate YES. If there are additional bags left frozen after the second infusion, Q33 will be no, and Q36 will indicate what remained frozen.

Do I need to report the Cord Blood Bank (Q270) for related and autologous cord blood units?

Yes. CIBMTR is expected to provide outcome data back on these units as well (for regulatory reasons) and this information is required so that the information can be distributed correctly.

Why are there so many ID fields on the 2006, and what gets reported where?

The purpose of the IDs fields on the 2006s is to capture the information on exactly what product's information is being reported. It is very important that each 2006 include the information needed to uniquely identify the product involved. Because the form 2006 captures information on marrow, PBSC, and Cord blood products, as well as for autologous, related, and unrelated donors, there needs to be a way to capture the information needed for identification for each of these combinations. For cord blood units, this also means providing information on the source of the cord blood unit when the transplant is not facilitated by NMDP. Questions 266-280 need to be answered for all cord blood units where shipment was not facilitated by the NMDP. For NMDP transplants, this information is captured as part of the NMDP standard process.

How would one answer question 31 for an allo-donor product that was collected locally?

Because you are answering the questions on the forms from the perspective of the transplant center only, for products that were collected by your collection site and frozen, Q31 would be answered NO.

Should we report cell counts uncorrected or corrected for viability? Many flow procedures analyze only viable cells, so the absolute numbers on the flow reports are likely corrected, however, for nucleated cells this could vary a lot.

If your assay only measures viable cells, report that along with a viability number of 100% in the lower boxes. If the assay measures all cells, and then checks viability, report the total numbers, and report the percent cells that are viable.