CIBMTR® CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Appendix D. Corrective Action Requirements

Review the Corrective Action section (Appendix C) of this report for additional direction. Print this section of the report, address each item listed, and send a signed copy of this page and supporting materials to your auditor.

Disease Status Data Fields

Develop a plan to increase the accuracy of data submitted in disease status data fields.

✓ Errors in reporting disease status and assessment could be reduced by ensuring all staff have a thorough understanding of disease status criteria and the resources available to them, as well as an understanding of assessment methods and results. Establish a resource, training process, and/or procedure to ensure all staff completing the forms are familiar with disease status criteria and guidelines for reporting disease assessments. Submit documentation outlining a plan to improve disease status and assessment reporting.

Preparative Regimen Data Fields

✓ ***Develop a plan to increase the accuracy of data submitted in preparative regimen data fields.***

Errors in reporting preparative regimen data fields accounted for 28.8% of all critical field errors and were caused by failing to report the preparative regimen for the recipient's transplant. Submit documentation outlining a plan to improve preparative regimen reporting.

Karnofsky/Lansky Performance Score Data Fields

Develop a system to capture the pre-transplant Karnofsky/Lansky Performance Score.

✓ Out of the eleven recipients audited, seven had missing documentation used to verify the Karnofsky/Lansky Performance Score (KPS) reported at the pre-HCT time point. Missing documentation follow-up resulted in changes to reported scores based on retroactive evaluation and documentation of each recipient's KPS. Options recommended by the CIBMTR to develop consistent reporting include: use of progress notes with a specific area for the score for each visit or a stamp or label that can be used in the medical record as well as the outpatient and research charts. These alternatives would provide a visual reminder to those documenting the Karnofsky/Lansky score in the medical record. Submit documentation outlining the plan to capture the Karnofsky/Lansky Performance Score.

Consent Items for Other Recipients (Not Selected for Audit) *(continued)*		
CRID	Consent Form	Issue(s) & Action(s)
2811059	DTA	I attest that CIBMTR may use the data for this CRID submitted under the Data Transmission Agreement for research purposes. ☐ YES ☒ NO Signature of Data Manager Date:
2883884		I attest that CIBMTR may use the data for this CRID submitted under the Data Transmission Agreement for research purposes. ☒ YES ☐ NO Signature of Data Manager Date:

I attest that each item in the Corrective Action section was appropriately addressed and corrective action will be implemented.

Medical Director: _____ **Date:** _____

Return the attached Corrective Action Requirements section and supporting materials by **2013.** The Corrective Action materials may be submitted for review by the CIBMTR audit department via e-mail, fax, or mail.

CIBMTR Auditor Contact Information

Senior Clinical Research Associate

Minneapolis, MN 55413

E-mail:
Fax:

Corrective Action Plan submitted to CIBMTR

Disease Status Fields

"Develop a plan to increase the accuracy of data submitted in disease status data fields."

Root Cause Analysis:

Inadequate training in policy, standards, regulation, or other decision-making criteria.

Action:

The current data manager will review the FormsNet 3 Recipient Module Application Training module as well as the Instructions for Pre-Transplant Essential Data (Pre-TED) Form and the Instructions for Post-Transplant Essential Data (Post-TED) Form. This information will be disseminated to any other staff that is completing forms in the future. This will be added to the competency checklist in place for transplant nurses as well as the competency checklist for the therapeutic apheresis coordinator.

Timeline:

Immediate: Coordinator will review FormsNet 3 Recipient Module Application Training module as well as the Instructions for Post-Transplant Essential Data (Post-TED) Form.

October : A statement of completion/competency will be added to the Infusion RN II and Coordinator checklist.

Corrective Action Plan submitted to CIBMTR

Preparative Regimen Data Fields

"Develop a plan to increase the accuracy of data submitted in preparative regimen data fields."

Root Cause Analysis:

Inadequate training in policy, standards, regulation, or other decision-making criteria.

Action:

The current data manager will review the Instructions for Pre-Transplant Essential Data (Pre-TED) Form. A hardcopy of this manual will be printed and available for reference during entry of the preparative regimen data fields. This information will be disseminated to any other staff that is completing forms in the future.

Timeline:

Immediate: Coordinator will review Instructions for Post-Transplant Essential Data (Post-TED) Form.

Karnofsky/Lansky Performance Score Data Fields

"Develop a system to capture the pre-transplant Karnofsky/Lansky Performance Score"

Root Cause Analysis:

Inadequate training in policy, standards, regulation, or other decision-making criteria.

Action:

Immediate: The mobilization order set used for each disease site will be updated to include a required entry of the Karnofsky Performance Score. This field will replace the one currently asking for the ECOG Performance Score. A copy of the conversion from ECOG to Karnofsky will be available through the Coordinator should the ordering physician have any questions on the conversion.

Progress on CAP Implementation

INTRODUCTION

Before discussing our progress on the CAP plan for data entry improvement, we think it's important to let you know about some key facts related to this issue.

1. The new clinical/collections team that was gathered in late 2015 and working throughout 2016 to seek FACT accreditation was unaware a CIBMTR audit had taken place in 2013; that the program had failed that audit; and that a corrective action plan had been put into place for which we had continued accountability.
2. As a new clinical/collections team we were starting from scratch. We reviewed and evaluated existing policies and procedures in all applicable areas including data management and either modified them or developed new ones to satisfy requirements under FACT standards. We also put into place our own audit structures based on what we understood the FACT standards to be.
3. We remained unaware of our obligations for a Corrective Action Plan (CAP) until the Quality Manager was first able to review the data management requirements for the Annual Report on the FACT website in late December 2017. After conversations with our FACT advisor/consultant, Sarah Litel-Smith, we contacted CIBMTR to obtain copies of the CIBMTR audit from 2013 and the Corrective Action Plan that had been developed by a previous team.

We have now reviewed both the failed CIBMTR Audit from 2013 and the subsequent CAP. We think that the processes and practices we have instituted on our own to ensure strong and robust data management and reporting, without the benefit of knowing about the existence of the CAP material, will address the problems previously identified, and will demonstrate acceptable follow-through. We have listed these actions in the next section.

DATA MANAGEMENT PROCESSES IMPLEMENTED BY THE NEW TEAM

We have listed below some of the actions we have taken to address evolving data management issues as we worked together to prepare the program's readiness to seek FACT accreditation.

1. We designed a Review Form to be completed by the attending physician, as part of our multidisciplinary review for all potential HPC candidates. The purpose of the form is to pull together some of the key data that must be reported to CIBMTR into one central location. The form includes specifically a required field for the Karnofsky score. To make it easier for the physicians who are more comfortable with using ECOG scoring, we attached a conversion table on the back of the form. We are continuing to build upon this process and will be presenting additional features and modifications to this form as well as the introduction of some new data gathering options to our physicians at our next quarterly HPC Operational Council meeting which focuses specifically on physician and clinical management issues. Our plan is to bring physicians closer to the data reporting arena so that they better understand how they can contribute more effectively to this process and we can build consistency into the documentation that's used as source data.

2. We put in place a regular TED self-auditing structure which occurs at least annually and twice annually when patient volume permits additional frequency. Note: the audit included in this upload was done without the benefit of knowing about the CAP, but it demonstrates the attention we are paying to ensure accurate data. Other TED audits have focused on a smaller range of items.
3. The current Coordinator has been actively engaged in acquiring and refining her data management skills. She has developed a good working relationship with our CRC at CIBMTR and has taken advantage of the multiple learning opportunities offered by CIBMTR through its webinars. She also has developed strong working relationships with the Clinical Program Director and other transplant physicians. She has solid communication skills and does not hesitate to ask for additional information when it's needed. We think that lack of communication contributed to past mistakes – the previous data manager tried to figure things out on her own rather than ask questions of the physicians.
4. Last year, the Quality Manager attended the FACT Quality Boot Camp in Orlando as part of the ASBMT Tandem meetings. This year the Coordinator will be attending the FACT Quality Boot Camp at this year's Tandem meetings in Salt Lake City. She also will be attending some of the data and clinical meetings as well. Both of these actions contribute toward filling some of the training gaps identified as the "root cause" of the failed audit.
5. The Quality Manager has mentored and provided additional training to the Coordinator regarding IRB review requirements and processes including handling and safeguarding patient consenting procedures. The Coordinator is responsible for both submission of data to CIBMTR (i.e. TED forms data entry) and coordinating the patient consenting process. We believe that consents obtained in 2016 and forward will not demonstrate the problems identified in the failed audit from 2013.

REVIEW OF THE CAP WITH MODIFICATIONS

A few of the actions as described in the CAP have been further modified in the interim to better address data accuracy. Each submitted requirement/action is listed below in italicized font. Our comments regarding progress or modification are in non-italicized font.

1. ***"Develop a plan to increase the accuracy of data submitted in disease status fields."*** **Action:** ***"The current data manager will review the FormsNet 3 Recipient Module Application Training module as well as the Instructions for Pre-Transplant Essential Data (Pre-TED) Form and the Instructions for Post-Transplant Essential Data (Post-TED) Form. This information will be disseminated to any other staff that is completing forms in the future. This will be added to the competency checklist for transplant nurse as well as the competency checklist for the Coordinator."***

   These items have been accomplished except for adding a review of these documents to the competency checklist for all transplant nurses. Since transplant nurses have no responsibilities for data entry, we do not think this will be particularly effective and therefore will not be undertaken. A better solution will be to get information concerning how CIBMTR wants data

captured into the hands of physicians who make the clinical decisions regarding disease status, response to treatment, etc. and include clear documentation regarding those decisions in their progress notes. This process is currently underway.

2. **"*Develop a plan to increase the accuracy of data submitted in preparative regimen data fields.*"** **Action: "***The current data manager will review the instructions for Pre-Transplant Essential Data (Pre-TED) Form. A hardcopy of this manual will be printed and available for reference during entry of the preparative regimen data fields. This information will be disseminated to any other staff that is completing forms in the future."*

   This was accomplished. We further update the FormsNet3 Manual as changes are made and maintain hardcopy versions of reference manuals for all of the data entry items for which we are accountable (2400, 2402, and 2450). We continue to place this information in front of physicians so that we all are on the same page regarding required elements of documentation.

3. **"*Develop a system to capture the pre-transplant Karnofsky/Lansky Performance Score.*"** **Action: "***The mobilization order set used for each disease site will be updated to include a required entry of the Karnofsky Score. This field will replace the one currently asking for the ECOG Performance Score. A copy of the conversion from ECOG to Karnofsky will be available through the Coordinator should the ordering physician have questions on the conversion."*

   This was accomplished in 2013 and the Karnofsky score remains a required element on the order sets. However, we've taken this a step further and have placed this as a required field on our Review Form which includes the conversion table on the back so that physicians have all the information they need to convert an ECOG score to a Karnovsky score immediately at their fingertips.

AUDIT SUMMARY

			Form#
Audit Title:	*CIBMTR Audit*	**Type Audit:**	Semi –Annual – Key Element
		Date Assigned :	2017
Facility:	Clinical Program	**Staff Assigned:**	Quality Mgt.
Audit Period:	2016-2017	**Start Date:**	2018
Parameters:	Review TED Forms 2400, 2402,and 2450 (100 day) for 16 consecutive transplant patients CY 2016-2017	**Completion Date:**	2018

Audit Summary Description: -- TED forms (2400, 2402, and 2450 @ 100 days) were reviewed for 16 consecutive transplant patients from CY 2016 and 2017 to assess accuracy of data submitted to CIBMTR. An additional two cases from late 2017 were not included in the audit because Form 2450 was not yet available to review for those cases. Selected cases included the diagnostic categories of multiple myeloma and other plasma cell disorders as well as lymphoma (both HL and NHL) with multiple myeloma accounting for 75% of the cases reviewed.

Approximately 80 data elements were selected for review for each patient (n=1,280) with 60 of those elements or 75% (n=960) categorized as "Critical Data Fields" (CDF) by CIBMTR. Comparisons were made between the data as submitted to CIBMTR against original source information found in the patient's medical record.

By design the "Critical Data Fields" selected included many of the same fields referenced in an earlier, external audit conducted by CIBMTR in . This allowed us an opportunity to evaluate current program performance relative to specific problems identified in the past under a different administration. Importantly our team has only recently become aware of this prior report.

Errors will be reviewed with the Coordinator and Clinical Program Director and data corrections to CIBMTR will be made, per policy, as indicated.

Major Findings and Discussion:
A total of 28 errors were identified across all fields for an overall total error rate of **2.18%.** Looking at just the critical data fields, the error rate climbs a little higher to **2.6%**, but still within the expectations established by CIBMTR to not exceed a **3%** error rate. The table below details specific errors by type and quantity.

Error Item	Field Type	# Times	Error Item	Field Type	# Times
Diagnosis Date	CDF	2	Preparative Regimens	CDF	0
Karnofsky Score	CDF	1	Palifermin Orders/Administration	CDF	1
Consent Issues	CDF	1	Post HCT Disease Assessment (i.e., at follow-up)	CDF	11
Staging Issues	CDF	1	Additional Treatment Planned	CDF	2
Pre-HCT Disease Status	CDF	6	Other -- co-morbidities, start date, specific test results	Non-CDF	3

The table demonstrates that we have improved in many of the areas identified as problematic in the prior external CIBMTR audit conducted in before most of the current team was in place. However, in two

distinct areas we have some important work to do. You will note that just two critical data field areas account for 68% of the critical data field error rate above – Pre-HCT Disease Status and Post HCT Disease Assessment. These 2 areas directly relate to each other, such that an error in determining pre-HCT disease status usually portends errors will be made in determining post-HCT disease status as well because one feeds to the criteria for determining the other resulting in a cascading effect. Reviewing the previous CIBMTR audit was instructive in evaluating root causes for our current problem because the causes identified by CIBMTR in the prior audit remain the core reasons for our current errors:

1. *Complete remission (CR) data fields capture whether the recipient achieved CR as a direct response to transplant and planned therapy and the date CR was achieved or assessed. Errors resulted from reporting a CR was achieved post-transplant but the required assessments (as determined by the international working groups) to establish CR were not performed. Additional errors resulted from reporting that a recipient had not been evaluated during the reporting period, but evaluations performed during the reporting period indicated that a CR had been achieved.*
2. *Pre-transplant disease status fields capture recipient disease status immediately prior to the start of the preparative regimen. Half of the errors identified in these data fields resulted from reporting disease statuses that were not consistent with the disease response criteria established by the international working groups.*

For example, a frequent error made by our team was noting a CR had been achieved pre-HCT for multiple myeloma, when no bone marrow biopsy had been performed or was not available as documentation as required by the International Working Group criteria. Another common error was reporting all FISH and Flow Cytometry results for post HCT assessments when the manual instructions state to report results in those fields only when positive. Finally some errors were made because it is difficult to locate outside documents in the scanned materials, so existence of evaluations done elsewhere may be easily missed.

Short Term Recommendations:

Review with transplant physicians and the Coordinator the required response criteria for each specific disease type developed by the international working groups. Make these documents easily accessible to all involved.

Develop an effective means to easily locate and review documents coming from outside treatment facilities relating specifically to HPC patients. One idea might be to have all documents obtained from other treating facilities regarding stem cell patients expedited to the Coordinator for review and duplication of key data points prior to sending the documentation to medical records (HIM) for scanning.

Long Term Recommendations:

Develop a standardized template for information gathering related to CIBMTR data submission at various time points. This will build upon and be similar to work already done with physicians involving the *Review Form*. The template should include references to the source material and location and could be helpful in providing a consistent record of the course of treatment, expediting data entry and audits both internal and external.

Some errors may exist due to different sources of information being used by different decision makers. Since key pieces of information can be found "multiple times" in "multiple areas" within the EMR, and the documentation is not always consistent, recommend that primary, secondary and tertiary data source documents be identified for extracting information for key data elements for CIBMTR submission. This will help to eliminate confusion regarding which source to use and in what hierarchy.

AUDIT SUMMARY

Form#

SIGNATURES	
Auditor:	**Date:** 2018
Quality Manager:	**Date:** 2018
Clinical Program Director:	**Date:** 18
Follow-up Due:	2018