Building a Data Management Training Program for Initial Hiring, Onboarding and Ongoing Competency

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University of Miami Sylvester Comprehensive Cancer Center
TCT Clinical Research Professional / Data Management Conference
Disclosures

• No relevant disclosures
Learning Objectives

- Explain the various steps utilized to develop a comprehensive educational plan
- Identify rationale for providing an integrated approach to data management onboarding
- List the benefits of having a comprehensive onboarding plan for data management
Pillars of Success
Limited Hiring Pool

Demand
Expansion of
TCT
Increased data
capture

Supply
Qualified DMs

• Qualified TCT Data Manager
  – Comprehensive knowledge of:
  • Transplantation and Cellular Therapy
  • Hematology / Oncology
  • Research
  • Data Collection and Quality
  • Technical knowledge
2011 - BMT Program opens at UMHC; 58 transplants; 2 DMs

2012 – 96 transplants

2013 – 132 transplants

March 2016 – 4 DMs / 3 solely forms

2015 - Autologous Reporting Mandate; 171 transplants

2016 - Cleared Autologous backlog; 178 transplants

2017 - Concurrent Reporting; 202 transplants

June 2018 – Turnover, down 2 DMs

2018 - Cellular Therapy Reporting; 221 transplants

• Rapid Growth
• Turnover/Loss of seasoned DMs
• No centers to poach form
• No formal training programs
Hiring

• Identified key characteristics for potential hires:
  – Demonstration of the University of Miami Core Values
  – Hard skills: clinical, research, quality, registry or regulatory experience
  – Soft Skills: critical thinking, problem solving, and initiative
  – 2 Year commitment
Development of Training Program

- Competencies
- Education Plan
- Orientation
Competency

• Utilized CIBMTR Data Collection Forms and Forms Manual as a foundation

• Leveraged the experiences of current data managers to determine the content of competencies

• Mapped internal transplant process from a data management perspective

• Adapted format from nursing competency checklist
Competency

Adult Stem Cell Transplant Program
Research Data Manager
Initial Competency and Validation

<table>
<thead>
<tr>
<th>EMPLOYEE NAME:</th>
<th>DATE:</th>
<th>TITLE:</th>
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</table>

**NOTE:** This is a representative sampling of the competencies necessary for safe, effective performance.

<table>
<thead>
<tr>
<th>SELF ASSESSMENT:</th>
<th>COMPETENCIES:</th>
<th>METHOD OF EVALUATION KEY:</th>
<th>LEVEL OF COMPETENCE:</th>
</tr>
</thead>
</table>
| K                | The employee will demonstrate the following skill competencies listed below | A. Post-test
B. Return Demonstration
C. Observation of Daily Work
D. Case Study
E. Exemplar
F. Discussion/Reflection Group
G. Mock Event
H. Presentation
I. Quality Improvement
J. Monitor
K. Other | 1. Met objective
2. Met objective with minimal assistance
3. Not met (see action plan) |

**K**
1. No experience

**E**
2. Some experience/needs practice

**Y**
3. Can safely perform without supervision

**Note:** Competencies should be written using measurable verbs (i.e. demonstrate, comprehends, understands, provides, displays).
<table>
<thead>
<tr>
<th>Department Specific Initial Skill Competencies</th>
<th>Self-Assessment</th>
<th>Date</th>
<th>Measure</th>
<th>Initials</th>
<th>Level of Competence</th>
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<tbody>
<tr>
<td><strong>Transplant Specific or General Objectives</strong></td>
<td>N/A</td>
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<td>2</td>
<td>3</td>
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<td><strong>Basic Knowledge for Hematopoietic Progenitor Cell (HPC) Transplantation</strong></td>
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<td>Understand rationale for type of transplant and the determination process (Autologous vs. Allogeneic)</td>
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<td>• Indications for autologous transplant and rationale</td>
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<td>o Disease Indications</td>
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<td>o Rationale for HSCT after conditioning</td>
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<td>• Indications for allogeneic transplant and rationale</td>
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<td>o Rationale for HSCT after conditioning</td>
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<td>o GVL effect</td>
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<td><strong>Selection of Suitable Recipient (B3.3.4.2)</strong></td>
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<td>Understand selection of suitable recipients</td>
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<td>• HCT Comorbidity index</td>
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<td>• Donor evaluation and management (B3.3.4.3)</td>
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<td>o NMDP Registry</td>
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<td>o Rationale for using MRD vs. MUD vs. MMUD vs. Haploidentical</td>
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<td>• HLA Typing</td>
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<td>o Basic understanding of the HLA matching process</td>
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<td>o Rationale for HLA typing</td>
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<td>o Matched donor vs. Unmatched donor</td>
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<td>o Minimum HLA Matching Requirement</td>
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<td>o Understanding of MHC type 1 and type 2</td>
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<td>o Locate HLA report</td>
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<td>Department Specific Initial Skill Competencies</td>
<td>Self-Assessment</td>
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<td>Measure</td>
<td>Initials</td>
<td>Level of Competence</td>
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<td>• Organ specific toxicities</td>
<td>N/A</td>
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<td>• Infections</td>
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<td>Cellular Therapy (non-HSCT)</td>
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<td>Understand the following concepts associated with CAR-T and other novel cellular therapy treatment modalities:</td>
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<td>• Cytokine Release Syndrome (CRS)</td>
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<td>• Neurotoxicity (NT)</td>
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<td>• Grading and management of CRS</td>
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<td>• Locate CRS and NT flowsheets</td>
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<tr>
<td>CIBMTR / Data Management Processes</td>
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<td>Comprehend and perform the following data management processes and tasks:</td>
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<td>• Admission Flow</td>
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<td>○ Accession Log</td>
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<td>○ Velos</td>
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<td>○ Forms: 2804, 2814, 2400, 2402, Baseline forms</td>
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<td>○ Randomization: TED vs. CRF</td>
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<td>• Follow-up Flow</td>
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<td>○ Forms: 2450, 2100, 211x</td>
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<td>○ Send fax requests to outside providers</td>
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<td>• Platelet Engraftment</td>
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</table>
# Disease Specific Objectives

**Acute Myelogenous Leukemia (AML)**

- Know disease process for AML
- Distinguish between AML subtypes
- Understand tests required for diagnosis and management
  - CBC/Peripheral smear
  - Bone marrow
  - Molecular (i.e. BCR-ABL)
  - Cytogenetics (Karyotype & FISH)
  - Flow Cytometry
- Explain testing used to identify minimal residual disease
- Understand disease staging and response criteria (basic terms of remission)
- Identify treatments for AML including treatment intent/purpose
- Review and be familiar with the following forms:
  - 2402 – AML section
  - 2010/2110

**Acute Lymphoblastic Leukemia (ALL)**

- Know disease process for ALL
- Distinguish between ALL subtypes
- Understand tests required for diagnosis and management
  - CBC/Peripheral smear
  - Bone marrow
  - Molecular
  - Cytogenetics (Karyotype & FISH)
  - Flow Cytometry
- Explain testing used to identify minimal residual disease
- Understand disease staging and response criteria (basic terms of remission)
Education Plan (EP) [Lesson Plan]

• Used competencies as roadmap for lesson plan

• Designed the EP as a stepwise approach with opportunities for discussion, evaluation, and the application of knowledge.

• Reviewed reputable journals, articles, etc. to support the content

• Determined best teaching method as it related to the content
  – Lecture
  – Self-paced modules
  – Case Review (previously completed cases)

• Assigned an experienced DM as a preceptor for each topic
## Education Plan

<table>
<thead>
<tr>
<th>Start</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>End</th>
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</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
<td><strong>26-Aug-19</strong></td>
<td>8 am - 5pm DM Team</td>
<td>9 am - 11 am Intro to SCT - DM</td>
<td>8 am - 4 pm Cancer Basics</td>
<td>30-Aug-19</td>
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<td></td>
<td>- Housekeeping</td>
<td>- Department Orientation</td>
<td>Staff Meeting</td>
<td>SSB Room 160</td>
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<td></td>
<td>- Staff Meeting</td>
<td>11 am - 12pm Systems DB Engineer</td>
<td>1 pm - 5pm</td>
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<td></td>
<td>- Database Access</td>
<td>- Database Reports</td>
<td>- Meet w/ DM Manager</td>
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<td></td>
<td>- Database Access</td>
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<td>- Review Orientation Material</td>
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<td>- NMDP E-Learning</td>
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<td><strong>HOLIDAY</strong></td>
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<td><strong>HOLIDAY</strong></td>
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<tr>
<td><strong>Week 2</strong></td>
<td><strong>2-Sep-19</strong></td>
<td>9:00 am - 11:00 am DM Staff</td>
<td>8:30 am - 12:30 pm TCTP Coordinator</td>
<td>8 am - 12:30 pm TCTP Coordinator</td>
<td>6-Sep-19</td>
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<td></td>
<td>- Protocol Training</td>
<td>Manager</td>
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<td>1:00 pm - 5:00 pm Web-based Training</td>
<td>1:30 pm - 2:00 pm DM</td>
<td>1 pm - 5 pm Web-based Training</td>
<td>(Competency Sign Off - Need to Highlight</td>
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<td></td>
<td>- Introduction to HLA</td>
<td>- Telos Training</td>
<td>- CRID 2804</td>
<td>on Competency which ones)</td>
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<td></td>
<td>- Basic Biology of HLA</td>
<td>- HLA &amp; Chimerism Application</td>
<td>- Indication for CRID</td>
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<td></td>
<td>- Advanced Biology</td>
<td>- Final Typing DB</td>
<td>- Pre-TED Form 2400</td>
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<td></td>
<td>- Genetics of HLA</td>
<td>- Q&amp;A / Debrief</td>
<td>- Reporting Prep Regimen on 2400</td>
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<td></td>
<td>- HLA Reporting (Form 2005)</td>
<td>2:30 pm - 3:30 pm Independent Study</td>
<td>and Form 2000</td>
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<td><strong>Week 3</strong></td>
<td><strong>9-Sep-19</strong></td>
<td>8:00 am - 10:00 am Apheresis</td>
<td>8:00 am - 10:00 am DM Staff</td>
<td>8:00 am - 10:00 am Self Paced</td>
<td>13-Sep-19</td>
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<td>Manager</td>
<td>- Admission Process</td>
<td>- Admission Process</td>
<td>Learning</td>
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<td></td>
<td>- Collection Center</td>
<td>- Finance Manager</td>
<td>- Finance Orientation</td>
<td>- Case Reviews</td>
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<td>- Stem Cell Processing Lab</td>
<td>10:00 am - 11:00 am Finance</td>
<td>- Didactic training (lymphoma)</td>
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<td>Manager</td>
<td>- Lymphoma Case Review (CRID XXXX)</td>
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<td>- Finance Orientation</td>
<td>MRN XXXX, Patient Name - Mantle cell</td>
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<td>12:00 pm - 5:00 pm Webinars</td>
<td>Reviewed 2400- DM Staff - Assigned to look up</td>
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<td>- Lymphoma Pre-Infusion</td>
<td>LDH (lab) and read on Cytogenetics in</td>
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<td>- Lymphoma Post Infusion</td>
<td>the manual</td>
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<td>- Cellular Therapy</td>
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**CIBMTR**

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

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**CRP/DM CONFERENCE 2021**

**15**
Orientation Plan

• Set an expectation that new hires would have an observational rotation through the clinical and non-clinical areas of the transplant program

• Used transplant flow as the basis of programmatic orientation

• Identified key individuals from each of the departments and set the objectives/key topics they would cover with new hires

• Aligned orientation schedule to coincide with topics in education plan
Summary

Competencies

Development
• Based on prior DM experience
• CIBMTR data collection forms and manual = foundation
• Format adapted from nursing

Execution
• 10-page (landscape) competency checklist
• 2 main categories:
  • Transplant Specific & General Objectives
  • Disease Specific & General Objectives

Education Plan

Development
• Based on competencies
• Used varied approaches for effective learning
• DM preceptor assigned for each topic

Execution
• Detailed schedule of assigned topics, preceptors, and method of training

Orientation

Development
• Mapped transplant process from data management perspective
• Identified key individuals
• Established objectives for rotation
• Aligned rotation schedule with education (lesson) plan

Execution
• Schedule of clinical and non-clinical areas to be observed
• List of point of contacts for each area in transplant program
Culmination and Execution of Training Program

• Successfully onboarded 3 novice data managers in the span of 12 months

• Each data manager was given an Orientation Folder containing:
  – Data Management Orientation Checklist
  – Education Plan (calendar of assigned topics)
  – Interdepartmental Orientation Schedule (calendar)
  – Data Management Competencies
  – Organization Chart
  – Phone Rooster
  – Internal Data Management Manual
Culmination and Execution of Training Program

• New hires spent a minimum of 10 weeks in didactic training and 8 weeks of guided forms submission

• Competencies periodically reviewed and checked off by both new hire and preceptor

• Personalized education plans were developed to bridge knowledge gaps uncovered in evaluation phase
Example of Focused Study Guide for a Personalized Education Plan

Post-Transplant Complications

1. General
   - Identify common complications post-transplant and treatment
   - Define and understand each:
     - Neutropenia
     - Mucositis
     - Catheter-related complications

2. Infection
   - Transplantation related factors affecting the risk of infection. Refer to Table 1 [link]
   - Define the 3 phases for infection risk:
     - Pre-engraftment: 2-4 weeks post HSCT
     - Post-engraftment: 2-3 months post
     - Late phase: beyond 3 months after engraftment

Objectives

- Define each complication.
- Identify vaccination schedule post-transplant.
- Identify what infections/complications occur in each phase include neutropenia etc and rationale.
- Identify prophylaxis/treatment for each infection or complication, length of tx.
- Identify differences between treatment and prophylaxis (common medications, e.g. dosages).
- Identify causes and rationale for prophylaxis and infection risks.
- Identify laboratory tests available for each infection.
- Identify manifestations and/or presentation of each infection.

- Refer to [risk stratification] and management for further understanding.
- Post-transplant care recommendations (NMDP)

1. Infections: vulnerability to infection and immune reconstitution (finalizes 2-3 yrs post)
   a. Fungal (mold) infections
      i. Aspergillus – P/F
      ii. Non aspergillus
   b. Bacterial infections
      i. Bloodstream infections
      ii. GUT infections e.g. C-Difficile
      iii. Staph infections
      iv. Pseudomonas
Ongoing Competency

• Continued use of individual education plans beyond onboarding period
• Mandatory annual education in transplantation and cellular therapy
• Performance of data validation audits
• Case discussion and presentation
• Presence in clinical conferences (i.e., Tumor Boards, etc.)
Outcomes / Benefits

• Plan is structured, formal and reproducible
• Ensures consistency in training and knowledge base
• Establishes transparency and clearly outlines job performance and expectations
• Allows the department to be prepared for turnover and growth
• Helps to hard wire internal processes
• Creation of a center specific data management manual
THANK YOU!

Quality and Data Management Team