Conflict of Interest Disclosure

I attest that I have no relevant financial, professional, or personal relationship with a commercial interest producing health care goods/services related to this educational activity.

I will not discuss off-label use of commercial products.

Objectives

- Understand the necessary preparations for a CIBMTR audit
- Learn the CIBMTR audit and post-audit follow-up process
- Describe current trends in CIBMTR audit results
The Purpose of CIBMTR Audits

- Assess the quality and accuracy of the SCTOD/CIBMTR Research Database
- Identify errors in reporting data
- Implement corrective action plans to help prevent future errors
- Provide additional on-site training

Pre-Audit Timeline

End of Fiscal Year Prior to Audit
- Notice of upcoming audit
- Educational materials to Medical Director
- Medical Director assigns Primary Data Management contact
- Work with audit coordinator to schedule audit
  - Plan 3-4 days with 2 auditors
  - Plan 4-5 days with 1 auditor
Pre-Audit Timeline

8 – 10 Weeks Prior to Audit

- 16 transplants are randomly selected for audit review
- Transplants must have the Pre-TED and 100-Day report form complete (100 Day Post-TED or 100 Day Post-HSCT)
- Transplants must have occurred since the date of most recent audit
- Once selected, forms are locked in FormsNet2

Pre-Audit Documents: Pre-Audit Questionnaire

- Includes questions about:
  - Who/where to meet upon arrival
  - Working hours (normal hrs: 8am – 6pm)
  - EMR access
  - Wireless internet availability
  - Lodging recommendations
  - Chart organization (paper vs. electronic, inpatient vs. outpatient, GVHD, KPS, Consent)
Pre-Audit Documents: Transplant History List

- Complete list of all transplants performed at center since December 3, 2007.
- Used to evaluate submitted data to FormsNet
- Includes:
  - Date of HSCT
  - Type of transplant (Auto/Allo Unrel/Allo Rel)
  - Product Type

Pre-Audit Timeline

1 – 2 Weeks Prior to Audit

- Lead auditor or designee will contact primary data management to:
  - Discuss additional logistical details (i.e., where should I park? Who should I call upon arrival)
  - Discuss organization of the week
  - Ask any outstanding questions
  - Confirm arrival times

Pre-Audit - Data Management Responsibilities

- Request recipient medical records
- Paper charts from medical records
- Electronic Medical Records (EMR) access
- Arrange a work space for the auditors
- Return requested documents in a timely manner (Pre-audit Questionnaire, Transplant History List)
- Communicate any questions/concerns to audit staff
Pre-Audit Items NOT to be concerned about

- Do not need to flag records for source documentation
- Do not need to arrange meals or snacks
- Do not need to be too nervous about the audit/auditors
- Do not need to worry about asking too many questions

Presentation Overview

Audit Process

- Data submitted via FormsNet downloaded into Excel worksheet
- Auditor will select recipient to review in its entirety
- Source documentation from record compared to submitted data
- Auditor takes notes regarding any changes made
- Flag paper records for reference
Audit Process

- Source Documents
  - **ALL** inpatient, outpatient, & clinical progress notes
  - Laboratory evaluations
  - Pathology evaluations
  - Radiological evaluations
  - Outside progress notes, labs, etc.

Audit Process

<table>
<thead>
<tr>
<th>Field Types</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Field</td>
<td>Data in these fields is deemed critical to outcomes based research</td>
</tr>
<tr>
<td>Random Field</td>
<td>Randomly selected non-critical data field. Increased validity of audit</td>
</tr>
<tr>
<td>Non-Audit Fields</td>
<td>Data fields visible on audit worksheets, but not selected for audit</td>
</tr>
</tbody>
</table>

Audit Process

- **Discrepancy Error**
  - Data in medical record was different than data reported on the form
- **Omission Error**
  - Data in the medical record should have been reported on the form, but was omitted
- **Missing Documentation Error**
  - Data could not be verified based upon available medical records
Audit Process – Drug Dosing

- Review all drug dosages submitted on Pre-TED/Recipient Baseline Forms
- Any changes made to fields not selected for audit will not count against center (non-audit change)
- Differences in reporting on Pre-TED vs. Baseline
  - Pre-TED: Total prescribed dose in mg/m² or mg/kg
  - Ex: Cyclophos. 60 mg/kg * 2 doses = 120 mg/kg
  - Baseline: Total given dose in mg
  - Ex: Cyclophos. 3000mg * 2 doses = 6000 mg (50 kg recipient)

Audit Process – Consent Forms

- Ensure informed consent was given for
  - CIBMTR Research Database
  - CIBMTR Research Sample Repository
- All pages are present
- Signed and dated by recipient (or guardian, PoA)
- Signed prior to submission of data/collection of sample
- Signed within IRB approval time frame
- All of the blanks on the consent form are complete

Audit - Data Management Responsibilities

- Brief initial meeting
- Availability for questions
- Check in on auditors throughout the day
- Forward “medical” questions to clinical staff
- Closing meeting
- Ask questions
Audit – Closing Meeting

- Most helpful for those who complete forms
- Can arrange a short “high-level” overview for medical director if requested
- 1 – 2 hours on last day
- Discuss
  - Overview of audit process
  - Initial trends found during audit
  - Audit follow-up

Presentation Overview

Post-Audit Timeline

1 – 2 Weeks Following the Audit

- Request answers for outstanding questions
  - From the center
  - From CIBMTR experts
- Send out checklist for any missing documents
- Auditors begin report
  - Generate error correction forms
  - Data enter ECFs
  - Analyze the results of the audit
Missing Documentation Checklist

- Auditors send Data Management a list of data fields with missing documentation errors.
- Listed by CRID/question number/current value.
- Data Management address any outstanding missing documentation errors in 1 – 2 weeks:
  - Locate the missing source document and submit it for review.
  - Report that document cannot be located.
- Remaining MD issues will be addressed on Corrective Action Plan.

Post-Audit Timeline

6 – 8 Weeks Following the Audit

- Audit report sent to Medical Director and Data Management Staff.
- Audit report packets include:
  - Cover letter to MD.
  - Audit report.
  - Copy of Error Correction Forms (for Data Manager) for reference purposes.
  - Corrective Action Plan (if necessary).

Audit Report

- Overall, Critical, and Random Field error rates.
- By form and field type (critical vs random).
- By form and error type (discrepancy, omission, missing documentation).
- By form and reporting area.
- Discussion of errors.
- Comparison to previous audit.
- Consent form issues.
- Conclusion.
Audit Report

≤3%

Critical Field Error Rate

Corrective Action Plan

- Required when:
  - Critical field error rate > 3%
  - Systemic errors in one reporting area
  - Consent issues
- Opportunity to improve data accuracy
- Checklist identifies reporting and consent issues
- Request action plan from center to address reporting issue(s)
- Record and explain consent issue(s)

Locked Forms

- Forms locked in FN2 during randomization pre-audit
- Stay locked
- Change requests made through audit department
- Contact your lead auditor or audit coordinator to make changes
- Additional questions or source documentation review may be required
Post-Audit – Data Management Responsibilities

- Collaborate with colleagues to address items on Corrective Action Plan Checklist
- Submit Corrective Action Checklist/Plan to auditor
- Receive “Completion of Audit” certificate

Post-Audit Timeline

4 Years Following the Audit
- Audits are scheduled on a 4 year cycle
- New transplants will be audited (since the date of previous audit)
- Results reflective of changes following previous audit

Presentation Overview

- Pre-Audit
- Audit
- Post-Audit
- Update Audit Results
Data Included in Audit Results

- Related and unrelated allogeneic, and autologous transplant data since December 3, 2007
- Unrelated transplant data prior to December 3, 2007

Data NOT Included in Audit Results

- CIBMTR Milwaukee Legacy audit results are NOT included:
  - Related allogeneic and autologous transplants prior to December 3, 2007

Transplant Center Audit Results

Audit results are shown in **averages per cycle**

Audit cycles are four year periods:
- Cycle 1: 1998-2001
- Cycle 2: 2002-2005
- Cycle 3: 2006-2009
- Cycle 4: 2010-2013

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Error Rate</td>
<td>3.1%</td>
<td>1.8%</td>
<td>1.5%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Critical Field Error Rate</td>
<td>5.3%</td>
<td>3.1%</td>
<td>2.5%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Random Field Error Rate</td>
<td>2.6%</td>
<td>1.5%</td>
<td>1.1%</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

* Through June 2012
Transplant Center Audit Results

The critical error rate threshold was 5% until 2010 and 3% in 2011-present.

Current Cycle 4 Results

<table>
<thead>
<tr>
<th>Critical Error Rate</th>
<th>Total Centers</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 3% (≤5% in 2010)*</td>
<td>114</td>
<td>78%</td>
</tr>
<tr>
<td>&gt; 3% (&gt;5% in 2010)*</td>
<td>32</td>
<td>22%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>146</td>
<td></td>
</tr>
</tbody>
</table>

The critical error rate threshold was 5% for 2010 and 3% in 2011-present.

Current Cycle 4 Results

<table>
<thead>
<tr>
<th>Critical Error Rate</th>
<th>1st Audit</th>
<th>≥ 2nd Audit</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 3% (≤5% in 2010)*</td>
<td>52</td>
<td>62</td>
<td>114</td>
</tr>
<tr>
<td>&gt; 3% (&gt;5% in 2010)*</td>
<td>20</td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>72</td>
<td>74</td>
<td>146</td>
</tr>
<tr>
<td>% ≤ 3%</td>
<td>72%</td>
<td>84%</td>
<td></td>
</tr>
</tbody>
</table>

*Data from international center apheresis database.
### Current Cycle 4 Results

**Critical Error Rate**

<table>
<thead>
<tr>
<th></th>
<th>Domestic Center</th>
<th>Int’l Center</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\leq 3%) (\leq 5% \text{ in 2010})*</td>
<td>96</td>
<td>18</td>
<td>114</td>
</tr>
<tr>
<td>(&gt; 3%) (&gt; 5% \text{ in 2010})*</td>
<td>23</td>
<td>9</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>119</td>
<td>27</td>
<td>146</td>
</tr>
<tr>
<td>% (\leq 3%)</td>
<td>81%</td>
<td>67%</td>
<td></td>
</tr>
</tbody>
</table>

*Source from International Blood & Marrow Research*  
*Training & Development*

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### Current Cycle 4 Results

**Domestic Centers vs. International Centers**

<table>
<thead>
<tr>
<th></th>
<th>Domestic Centers</th>
<th>International Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Error Rate</td>
<td>1st Audit</td>
<td>2nd Audit</td>
</tr>
<tr>
<td>(\leq 3%) (\leq 5% \text{ in 2010})*</td>
<td>34</td>
<td>62</td>
</tr>
<tr>
<td>(&gt; 3%) (&gt; 5% \text{ in 2010})*</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>45</td>
<td>74</td>
</tr>
<tr>
<td>% (\leq 3%)</td>
<td>75%</td>
<td>84%</td>
</tr>
</tbody>
</table>

*Source from International Blood & Marrow Research*  
*Training & Development*

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### Current Cycle 4 Results

**Frequency**

- Total Fields Audited: ~928,000
- Discrepancy Errors: 11,296
- Missing Documentation Errors: 2,722
- Omission Errors: 6,471

*Through June 2012*

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*Source from International Blood & Marrow Research*  
*Training & Development*
Current Cycle 4 Results

### Missing Documentation Errors

<table>
<thead>
<tr>
<th></th>
<th>2010-2011 per center</th>
<th>19.5 errors per center</th>
</tr>
</thead>
<tbody>
<tr>
<td>So far in 2012*  per center</td>
<td>14.6 errors per center</td>
<td></td>
</tr>
</tbody>
</table>

* Through June 2012

---

Current Cycle 4 Results

### Corrective Action Plans Required

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>86%</td>
<td>14%</td>
</tr>
</tbody>
</table>

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Contact Information

Questions?

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612-884-8709