Source Documents
The Key to Quality Research Data
Objectives

- Definition
- Importance
- Real Life Scenarios
- Reporting Results
Definition

Original records or certified copies of clinical findings and observations
What does this definition mean?
Source Document

- Document in which data are first recorded
- Permanent record kept by physicians or institutions
- Used to complete Case Report Forms
Why are source documents important?
Importance of Source Documents

- Continuum of Patient Care
- Insurance
- Coding & Billing
- Litigation
- Clinical Trials
- Research Outcomes Database
What is considered a source document?
Examples of Source Documents

- Progress Notes & Consultations
- Face Sheet
- Referring Physician Correspondence
- Laboratory Reports
- Medication Administration Records
- Pathology & Radiology Reports
Examples of Source Documents (continued)

- Physician Orders
- Nursing I & O Flow Sheets
- Program Specific Forms
- Procedure Reports
- Transfusion Summary/Blood Bank
- Stem Cell Processing Records
- Radiation Therapy Records
Acceptable Formats of Source Documents

- Electronic Records
- Paper Records (Hard Copy)
- Photocopies
- Faxes
- Emails
- Telephone Communication Logs
Real Life Scenarios:

Which Source Document is Best?
Hierarchy

- Definitive
  - Source document with most conclusive evidence

- Accurate
  - Authored by highest member in chain of command

- Timely
  - Source document dated closest to event

- Consistency
  - Within reporting practices between patients
What if data is recorded on multiple source documents?
Scenario # 1
Reporting the Recipient's Infectious Disease Markers

- The recipient’s IDMs/Serologies are available in multiple locations:
  - Handwritten on a BMT Flow Sheet or Roadmap
  - Laboratory Report
  - Admitting History & Physical
  - Referring Physician’s Progress Note
Scenario # 1
Which source document is best?

- Handwritten on a BMT Flow Sheet or Roadmap
- Laboratory Report
- Admitting History & Physical
- Referring Physician’s Progress Note
Scenario # 2
Reporting the Recipient's Diagnosis Date

♦ The recipient’s diagnosis date is available in multiple locations:
  ♦ Referring Physician’s Progress Note
  ♦ Pathology Report
  ♦ Admitting History & Physical
  ♦ Discharge Summary
Scenario # 2
Which source document is best?

- Referring Physician’s Progress Note
- Pathology Report
- Admitting History & Physical
- Discharge Summary
Scenario #3
Reporting the Recipient's Neutrophil Engraftment

- The date of the recipient’s first ANC recovery post transplant is available in multiple locations:
  - Laboratory Report
  - Discharge Summary
  - Progress Note
  - Handwritten on a BMT Flow Sheet or Roadmap
Scenario # 3
Which source document is best?

- Laboratory Report
- Discharge Summary
- Progress Note
- Handwritten on a BMT Flow Sheet
What if data within source documents are inconsistent?
Scenario # 4
Reporting the Recipient’s Preparative (Conditioning) Regimen

◊ The total dose of Busulfan administered to the recipient is inconsistently documented:
  ◆ Chemotherapy Orders
  ◆ Medication Administration Record
  ◆ Admitting History & Physical
  ◆ Discharge Summary
Scenario # 4
Which source document is best?

- Chemotherapy Orders
- Medication Administration Record
- Admitting History & Physical
- Discharge Summary
Scenario # 5

Reporting the Severity of Acute GVHD

- Acute GVHD grading & staging is inconsistently documented:
  - Attending Physician’s Progress Note
  - Biopsy/Consult
  - GVHD Assessment Team’s Summary Sheet
Scenario # 5

Which source document is best?

- Attending Physician’s Progress Note
- Biopsy/Consult
- GVHD Assessment Team’s Summary Sheet
- All of the Above
Scenario # 6
Reporting Lymphoma Treatments Prior to Conditioning

- Pre-conditioning Lymphoma treatments are inconsistently documented:
  - Referring Physician’s Progress Note
  - Discharge Summary
  - Medication Administration Record
  - Admitting History & Physical
Scenario # 6
Which source document is best?

- Referring Physician’s Progress Note
- Discharge Summary
- Treatment Summary
- Admitting History & Physical
Scenario # 7
What if the source documentation is not available?
Scenario # 7
Post Transplant

- The patient is sent back to referring physician after transplant. Data sent to transplant center is limited or insufficient.
Scenario # 7
What should you do?

- **Do Not Report Undocumented Data**
- **Call Referring Physician – Request Additional Documentation**
- **Call the Liaison at your assigned CIBMTR Campus**
- **All of the Above**
Have data reporting practices improved over the past 10 years?
Source Document Audits
NMDP Audit Program
Quick Review

♦ Source documentation based audit
♦ Each TC audited once every four years
♦ Critical Fields
♦ Random Fields
♦ Error Rates
Cycle 1 and Cycle 2
Error Rates per Error Type

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Errors</td>
<td>3.00%</td>
<td>1.00%</td>
</tr>
<tr>
<td>Critical Field Errors</td>
<td>6.00%</td>
<td>2.00%</td>
</tr>
<tr>
<td>Random Field Errors</td>
<td>2.00%</td>
<td>1.00%</td>
</tr>
</tbody>
</table>

Error Rate %
Cycle 1 and Cycle 2
Total # of Errors per Error Type

- Overall Errors: Cycle 1 - 28560, Cycle 2 - 18614
- Critical Field Errors: Cycle 1 - 9221, Cycle 2 - 6263
- Random Field Errors: Cycle 1 - 19339, Cycle 2 - 12351
Source Document Wrap-Up

Utilizing Source Documents is the KEY to Quality Research Data!
Questions?
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