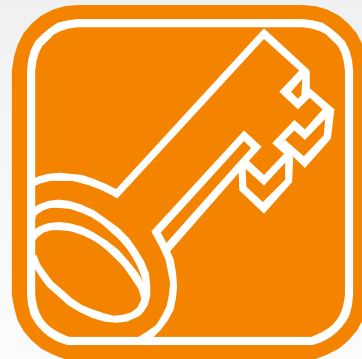


Source Documents The Key to Quality Research Data



CIBMTR[®]

CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

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?**

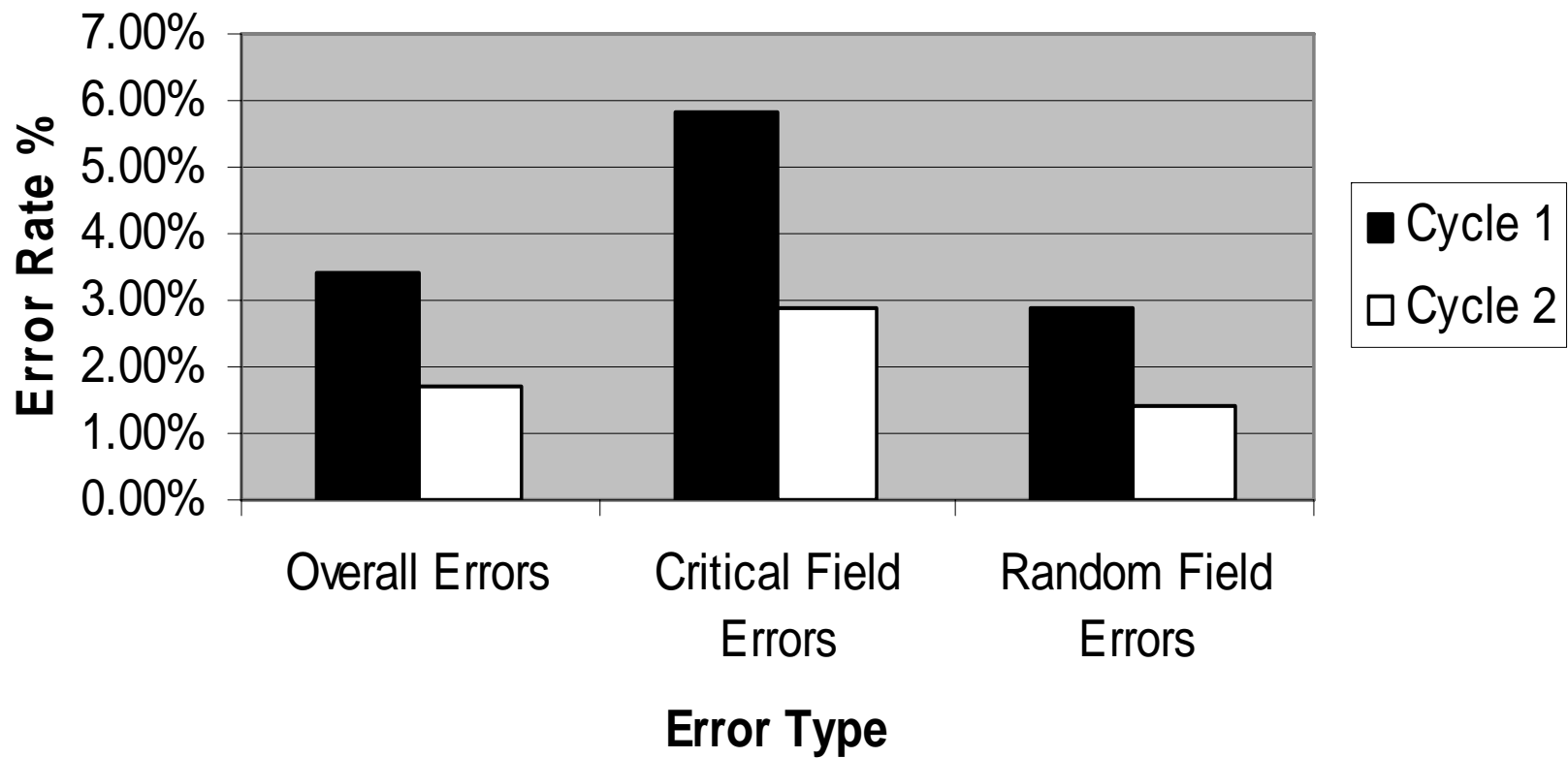
Source Document Audits



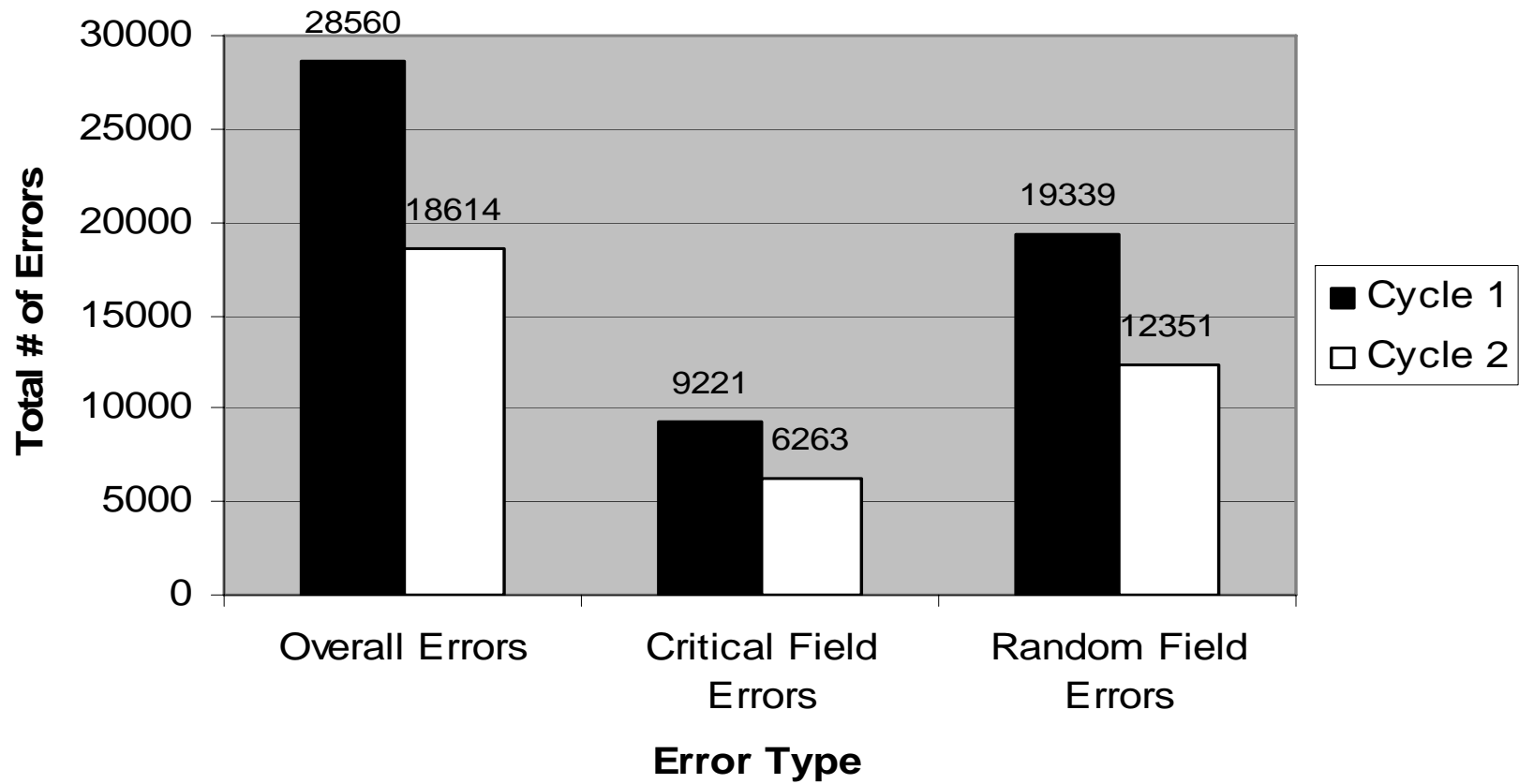
NMDP Audit Program Quick Review

- ◆ **Source documentation based audit**
- ◆ **Each TC audited once every four years**
- ◆ **Critical Fields**
- ◆ **Random Fields**
- ◆ **Error Rates**

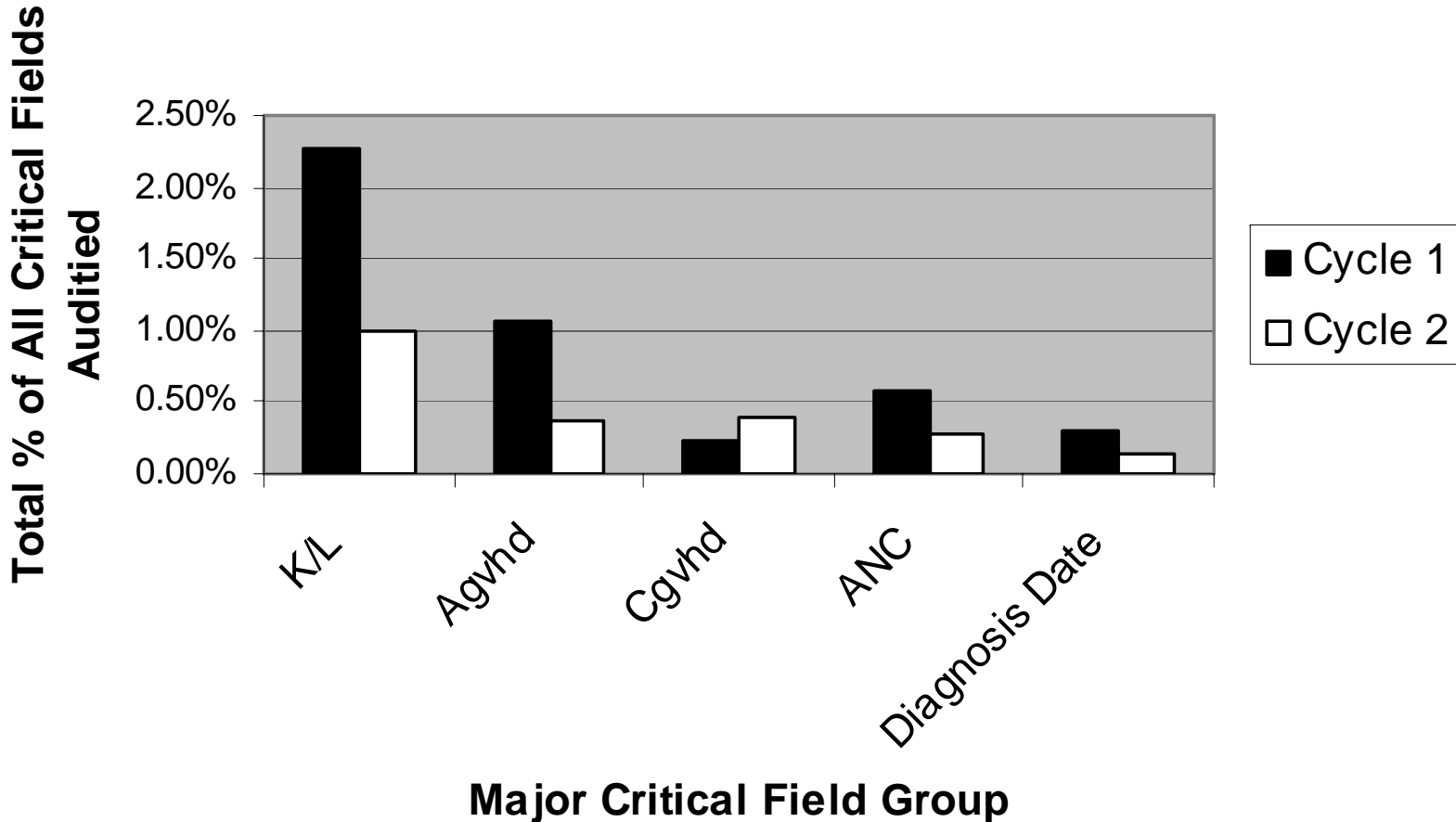
Cycle 1 and Cycle 2 Error Rates per Error Type



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

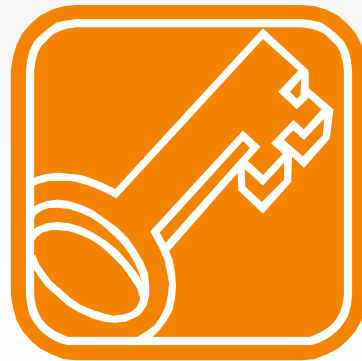


Cycle 1 and Cycle 2 Critical Field Error Rates



Source Document Wrap-Up

**Utilizing Source Documents
is the KEY to
Quality Research Data!**



Questions?

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