FACT-CIBMTR Data Audit Collaboration

• History of data audits
• The joint FACT-CIBMTR Task Force becomes a Committee
• The planned collaboration
• Potential impact on CIBMTR staff
• Questions
FACT-CIBMTR Data Audit Committee: Background

- FACT and CIBMTR have been performing independent primary on-site data audits for 20 years, with corrective action required for deficiencies.
- Processes have changed, yet:
  - FACT Clinical Inspectors cite programs for significant data accuracy problems.
  - CIBMTR continues to find Programs with >3% critical field error rates:
    - Some improve with next audit; others do not.
    - Programs currently “at risk” for consequences (>3% CER X 3) = 7.
- Approximately 72% concordance:
  - Programs with >3% CER also cited by FACT for data management deficiency.
  - Programs with FACT citations noted by CIBMTR to have >3% CER.
FACT – CIBMTR Data Audit Committee: Background

- FACT – CIBMTR Data Audit Committee formed to develop new processes to:
  - Facilitate improvements in data management and quality of data
  - Implement more severe penalties for non-compliance
  - Reduce burden of duplicative audits for Transplant Centers
  - Allow clinical inspectors more time on-site for other issues

- Purpose of this presentation:
  - Provide information about past and current FACT processes
  - Describe the proposed FACT-CIBMTR collaboration and timeline
  - Potential impact of project
  - Questions
B 4.000  DATA MANAGEMENT

B4.100  Each Program shall keep complete and accurate patient records.

B4.200  The records should include data of the type required and published by the International Bone Marrow Transplant Registry (IBMTR) or Autologous Bone Marrow Transplant Registry (ABMTR).

How to assess???
Assessment of Data Accuracy and Completeness

• Pick some data points
• Verify accuracy against source data at the Program
• Limitations:
  • It is only one Standard – must not require the whole day
  • Data points must seem important to applicant & inspector
  • Should be the same data as IBMTR collects
  • Programs need to know in advance which charts to prepare
FACT Assessment of Data Accuracy and Completeness

**AUTOLOGOUS RECIPIENT**

**ALLOGENEIC RECIPIENT**

<table>
<thead>
<tr>
<th>FACT Accreditation Program: Allogeneic Transplant Recipient Data Sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions: FACT Accreditation Program: Allogeneic Transplant Recipient Data Sheet. This program is designed to assess the accuracy and completeness of data entry for allogeneic transplant recipients. The program covers various aspects of patient care, including patient history, diagnosis, treatment, and outcomes. It is intended to be used by healthcare providers to ensure that all relevant data is captured accurately and completely.</td>
</tr>
</tbody>
</table>

1. **Patient Data**
   - **Patient ID**: [Unique Patient Identifier]
   - **Date of Birth**: [Date]
   - **Sex**: [Male/Female]
   - **Race**: [Asian/African American/Hispanic/Latino/Multiracial/Other]

2. **Diagnosis**
   - **Primary Disease**: [Type of Disease]
   - **Secondary Disease**: [Type of Disease]

3. **Treatment**
   - **Type of Treatment**: [Type]
   - **Intensity of Treatment**: [Low/Medium/High]

4. **Follow-up**
   - **Follow-up Schedule**: [Frequency]
   - **Follow-up Results**: [Results]

5. **Outcomes**
   - **Outcome Measures**: [Measures]
   - **Outcome Results**: [Results]

**Unique Patient Identifier**

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**FACT Accreditation Program: Autologous Transplant Recipient Data Sheet**

Instructions: FACT Accreditation Program: Autologous Transplant Recipient Data Sheet. This program is designed to assess the accuracy and completeness of data entry for autologous transplant recipients. The program covers various aspects of patient care, including patient history, diagnosis, treatment, and outcomes. It is intended to be used by healthcare providers to ensure that all relevant data is captured accurately and completely.

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5. **Outcomes**
   - **Outcome Measures**: [Measures]
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**Unique Patient Identifier**

**Page 1 of 2**
Original FACT Data Management Assessment

- Program submits list of transplant recipients for past year(s)
- Program selected 10 consecutive allogeneic and 10 consecutive autologous transplant recipients for data audit
  - Complete FAHCT form for each recipient – 10 data points per recipient
    - Data points important, reasonable for patient care, research, publications
    - Total: 100 – 200 data points, depending on type of transplants and Program size
- Clinical on-site inspector compared data to source data
  - Errors noted, reported to program, presumably corrected
  - Systemic errors or many errors → B4.100 citation on inspection report
  - Citation required documented corrective action prior to accreditation
FACT Assessment of Data Accuracy and Completeness

**ALLOGENEIC RECIPIENTS**
- Primary disease
- Preparative regimen
- Donor relationship
- Graft source
- Dose
- Engraftment date
- GVHD prophylaxis
- ?GVHD; ? histology
- Significant infection
- Survival

**AUTOLOGOUS RECIPIENTS**
- Primary disease
- Disease status at transplant
- High dose therapy
- Graft source
- Dose
- Ex vivo tumor cell purging?
- Engraftment date
- Post-transplant growth factor?
- Significant infection
- Survival
B 9.000 DATA MANAGEMENT

B9.100 The Program shall keep complete and accurate patient records.

B9.200 The Program shall collect all the data contained in the Transplant Essential Data Forms of the IBMTR/ABMTR. (See Appendix 1)

APPENDIX I

• TED-01 First Report: 100 Days Post Transplant
• TEDFU-01 Follow-up Report: 1 Year and Annually
FACT Data Audit Process – Version 2.0

- Eliminated unique FACT data sheets
- Verified accuracy using copy of TED forms
- Combination of data points audited:
  - Five specified; five randomly chosen by inspector
  - Same or different for each patient, each Program
- Clinical inspectors performed audits
- Part of a single day inspection
- FACT accreditation cycle: every three years
FACT Data Audit Process – Current Version

- Clinical inspector audits items from TED or MED-A forms
- Audit a minimum of 30 data points for each type of transplant
- Five data points for each patient identified; remainder random choice
  - Primary Disease; stem cell source; Donor type, engraftment date; survival
- Variability noted among inspectors
  - Choice of random fields, same or different for each record
  - Amount of detail recorded for FACT coordinators
  - Likelihood of citation
FACT – CIBMTR Audit Processes

**FACT**

• > 60 data points
• ~ 2 hours; one inspector
• 3 year cycle
• Consequences: potential loss of accreditation and loss of insurance coverage
• Inspectors:
  • BMT physicians (Peer to peer)
  • Trained in inspecting/Standards
  • Many diverse individuals
• Goal: verify “complete and accurate data”; educate Programs
  • Define “accuracy” according to their own knowledge in the field

**CIBMTR**

• >4,000 data points
• 3-4 days; 2-3 auditors
• 4 year cycle
• Consequences: data not included; scientists not allowed participation/leadership roles; possible NMDP would deny unrelated donors
• Auditors:
  • Minimum: bachelor’s-prepared
  • Trained and experienced in auditing
  • Consistent; limited number
• Goals: ensure quality and accuracy of research database and SCTOD; identify errors, ways to prevent; educate centers
  • Manual of Instructions to define potential answers
## CIBMTR – FACT Comparative Results 2012 – 2015

N=175 Programs

<table>
<thead>
<tr>
<th></th>
<th>FACT CITATION</th>
<th>NO FACT CITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CIBMTR &gt; 3.0% CER</strong></td>
<td>13 (7%)</td>
<td>30 (17%)</td>
</tr>
<tr>
<td><strong>CIBMTR ≤ 3.0% CER</strong></td>
<td>18 (10%)</td>
<td>114 (65%)</td>
</tr>
</tbody>
</table>

Audits Concordant = 7% + 65% = 72%
Discordant = 17% + 10% = 27%
FACT – CIBMTR Audit Processes

- Despite apparent differences, overall mission of the two organizations is the same: to improve quality patient care and outcomes in cellular therapy transplantation
- No audit detects every mistake; no system is perfect
- There are strengths and weaknesses to both FACT and CIBMTR processes
- Collaboration has potential benefits to
  - Transplant Programs
  - FACT
  - CIBMTR
  - Patients and public
A Work in Progress...

- FACT-CIBMTR Task Force to develop recommendations: March 2013
  - Chair: Dr. Daniel Couriel
  - Representatives from FACT and CIBMTR
- Task Force studied and compared FACT and CIBMTR processes and recommended:
  - CIBMTR should conduct data audits on-site on behalf of FACT and CIBMTR
  - FACT should retains its prerogative of determining impact of these results on a Program’s accreditation status
- FACT Board of Directors and CIBMTR Advisory Board each independently approved this Task Force recommendation: February 2015
- Task Force concluded; Data Audit Committee formed to further develop and implement the collaboration
- Continuous education!
FACT-CIBMTR Data Audit Committee

Co-Chairs: Phyllis I. Warkentin, MD
           Bronwen Shaw, MD, PhD

- Debra Christianson
- Daniel Couriel, MD
- Roberta King
- Vandana Rangnekar
- Sharon Robison
- Patricia Steinert

- David Vesole, MD
- Kathie Viers
- John Wagner, MD
- Victoria Whalen
- Heather Conway
- Linda Miller
All verification of data accuracy against source data will be performed by the CIBMTR audit teams according to current procedures and schedules.

FACT Clinical Inspectors will no longer perform a data audit on-site.
- Transplant programs will not need to prepare data sheets specifically for FACT.
- Transplant patient logs will be required to verify transplant numbers, types of transplants, age groups, transplant sites.
- Clinical inspectors will focus on implementation / adequacy of corrective action plans (CAP), internal data audits, and quality improvement.
- Clinical inspectors will have access to all CIBMTR results, and will review data management with clinical team.
Collaboration Essentials - 2

• FACT will assess Program’s data completeness and accuracy annually at the time annual reports or renewal compliance applications.
• Each Program will submit:
  • Dates of last three CIBMTR audits and results for:
    • Critical Field Error Rate
    • Random Error Rate
    • Overall Error Rate
    • Systematic Errors
  • Any CAP from most recent CIBMTR audit (except those relating to consent)
  • Progress report on the implementation of the CAP, including internal data audit of effectiveness of CAP
Collaboration Essentials - 3

- FACT and CIBMTR will use the same criteria for “acceptable performance” or assignment of consequences:
  - > 8% CER X 1
  - > 5% CER X 2
  - > 3% CER X 3

- FACT will assess timeliness and completeness of data by CPI reports from CIBMTR indicating “in good standing”

- FACT-CIBMTR Data Audit Committee will review information submitted to FACT, and will assess adequacy of CAP, documentation of implementation, adequacy and results of internal audits
  - Some details remain to be defined
  - Standardized assessment tools needed: to assess CAPs and measure improvement
  - Educational audit tools for programs may be useful
Collaboration Essentials - 4

• At the time of FACT accreditation renewal, the Accreditation Committee will evaluate a status report related to audit results that will include at least:
  • Most recent CIBMTR results for overall, critical field, systematic, and random error rates; CAP progress reports;
  • Most recent CPI results, showing “in good standing”
• FACT consequences will be phased in over time for programs that repeatedly fail to meet targets and fail to demonstrate improvement in data management
• Committee also aims to develop commendable practices guide and metrics for successful data management teams that could allow programs to obtain and maintain the resources needed for quality data management
A Work in Progress...

- August 2016: introductory, informational letter to FACT-accredited Programs, CIBMTR staff
- August and September 2016: FACT observations at CIBMTR audits
- September 12, 2016: CIBMTR Education Day
- Phase in new processes: Spring 2017
- FACT Inspector training: February 2017
- Data Audit Committee meets monthly to refine processes and begin to review results
A Work in Progress...

- Remaining issues:
  - Programs that do not report to CIBMTR – need a process to address data (international programs with FACT accreditation; autologous only programs)
    - Small number of accredited programs
    - Several alternatives – report to CIBMTR; additional on-site audit with accreditation ...
  - Criteria for improvement
  - Define measurements of process success
  - Timeline to suspend accreditation
  - Other details...
FACT-CIBMTR Collaboration: Potential Impact on CIBMTR Staff

- CIBMTR process is intended to stay the same
- On-site, you may get questions!
  - Be honest with what you know; refer personnel to FACT
  - Process will be as transparent as possible; let us know what you need
  - Staff Liaison is Heather Conway: heather.conway@unmc.edu
  - Can always contact me: pwarkent@unmc.edu
- You might feel scrutinized!
  - Remember we are all learning and trying to be helpful!
- You might be asked to help the Data Audit Committee
Benefits of Collaboration

- Minimize duplication of effort – inspectors and transplant centers
  - Programs are creating TED forms just for FACT
  - Reduce number of on-site inspections of data
- Reduce pressure on inspectors on-site
  - Allow them to concentrate on other/new elements of Standards compliance (e.g.: Outcomes)
- Take advantage of the strengths of each entity’s audit processes / consequences
- Need to continue data improvement; FACT provide added incentive
  - Currently, several (accredited) programs have >3% CER on 2-3 successive audits
- New processes created – added benefit
  - Increased scrutiny over implementation of CAP; internal audits – methodology, results
  - Continuous process – report annually rather than every 3-4 years
  - More opportunity to educate, assist
  - Discover / publish commendable practices
Questions?
Thank you.