Quality Management Plan for Collections

ISCT Annual Meeting
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Cost of Quality

- This is not the price of creating the quality product or service.

- It is the cost of NOT creating a quality product or service.
What are the costs to our donors if quality is not part of the collection process?

- Infection for the donor
- Contaminated product
- If labeled incorrectly the correct product may be infused into the incorrect recipient
- What other costs may exist?
How and where to start

- FACT offers detail in what they expect in your Quality Management Plan
  - Implementing is the challenge
- Start with the patient identification requirements
  - Use your facilities already established requirements
- What information do you want to record during the procedure
  - Items that may help in problem solving
    - Who did what at each step; time at which the step was performed
  - Items that may help for cost of quality issues
    - Was the procedure followed
How and where to start cont.

- What do you want the product to look like at the end of the collection
  - Hematocrit of product
  - Volume of product
  - Labeling requirements

- Review the completed product and paperwork to ensure it has met all of your quality requirements
  - Determine who will do this?
  - Determine how the data will be captured. Spreadsheet? Or Database? Think about the data integrity and how easy will it be to retrieve.
  - Document - How often? Daily, monthly, quarterly, yearly?
FACT Common Collection Citations

**Apheresis**
- C4: 31%
- C7: 17%
- C5: 17%
- C8: 12%
- C6: 7%
- C2: 10%
- Other: 6%

**Marrow**
- C8: 27%
- C4: 23%
- C5: 27%
- C7: 14%
- Other: 9%
Quality Management Citations in Apheresis Collection Inspections

- **Description of minimal trainer qualifications**
  - Needs to be included, or summarized and referenced, in the QM Plan
    - If included in QM Plan appropriately, inspector should be able to find the documentation
  - Description needs to be adequate
    - Describe what the minimal qualifications are as determined by the facility
Minimal Trainer Qualifications

- Inspectors often cannot find this description – if you include it in the QM Plan appropriately, the inspector should be able to find it because the details will either be right there in the plan or will direct the inspector to the applicable location.

- Also, the description needs to be adequate. It is not sufficient to state in procedures that trainers must meet minimal qualifications. The description needs to list what those qualifications are. It is also not enough to simply say a preceptor is a trainer – what makes the preceptor qualified? Be sure to describe this.
An example of Trainer requirements

- Trainers for each procedure should be technologists who either have developed the procedure or have been checked off for competency for said procedure.

- Any other examples?
Standard Operating Procedure Citations in Apheresis Collection Inspections

- Release and exceptional release
  - Definition of release is commonly misunderstood
  - Release as defined by FACT applies to Collection Facilities: removal of product from quarantine or in-process status when it meets specified criteria
  - Procedure often does not exist because Collection Facilities feel it does not pertain to them
    - Products “released” from the Collection Facility to the Processing Facility must meet specified criteria as defined by the Collection Facility
FACT Common Collection Citations

- Release and exceptional release
  - All products must meet established release criteria no matter if you are releasing to the floor for direct infusion or releasing it to the laboratory.
  - Examples if released to the lab may be:
    - Product is sealed completely without evidence of leakage
    - Product label is complete and correct according to expected data
    - Product has been stored appropriately
    - Donor eligibility determination documentation is available
Release Criteria

- Apheresis Collection Facilities are often cited because they do not have such a procedure because they feel that this particular requirement does not apply to them if they do not directly distribute products to clinical programs. However, release also applies to the release of a product to a Processing Facility.

- The Collection Facility must have criteria that must be met before they can release a product from in-process status (such as in the process of collection) to the Processing Facility. Such criteria may include that the appropriate content is on the label, that the collection bag has been verified to not be leaking, that there were no adverse events during the collection process, and many more.
If the product does not meet your established release criteria what and how will it be documented?

- Deviation
- Exceptional Release if being released to floor
FACT Common Collection Citations

- **Audits**
  - No evidence of audits being conducted
    - FACT’s minimum audit requirement is documentation of proper donor eligibility and determination prior to start of collection procedure
  - Lack of timetable of audits
    - Example – table of the audits you will do each quarter of the year
  - Lack of analysis to identify improvement opportunities
    - If you perform an audit and find an outlier complete a follow up and document the follow up
Audits

- Audits are often cited in both marrow and apheresis collection facilities. Probably the most serious deficiency is that there are situations in which there is no evidence of audits even being conducted. Facilities need to perform at a minimum the required audits listed in the Standards. Audits need to be documented and that documentation must be available to the inspector in order to verify compliance.

- Like clinical programs, programs do not always have a timetable for conducting audits. Remember, schedule actual dates for audits, include provisions for ad hoc audits, and focus on areas that have the most impact on patient safety.

- Finally, remember to use the audit results to identify improvement opportunities. Don’t let the time and resources you put into conducting an audit go in vain . . . The results should help your facility identify ways in which it can improve. As suggested before, use worksheets and forms to be sure all of the steps related to recognizing problems, detecting trends, and identifying improvement opportunities are completed.
Documentation of charts audited as part of the annual review process detailed in CTF-II-001 Quality Assurance Program. The listed forms should be present, complete (all data and initials), and reviewed (at appropriate time frames). Indicate compliance with "Y" or "N" in box provided with any additional information in Comments. Fields not applicable to the chart will be indicated by "N/A".

<table>
<thead>
<tr>
<th>Patient Service Month / Year:</th>
<th>Type of Apheresis (circle one):</th>
<th>Present</th>
<th>Complete</th>
<th>Reviewed</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Autologous</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Internal Allogeneic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collect/Process order</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certificate of Analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Declaration of Donor Eligibility</td>
<td></td>
<td>Present</td>
<td>Complete</td>
<td>Reviewed</td>
<td>Comments</td>
</tr>
<tr>
<td>Recipient/Physician signed letters for Ineligible Donors</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Consents</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FCTF-IV-025A Daily Pheresis Wrksht</td>
<td>FCTF-IV-003A Adverse Event during Apheresis, if applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Checklist for Audit of Stem Lab Entry of Critical Elements
Stem Cell Laboratory

Documentation of the completeness of data entry for the below critical elements. One chart from each calendar year month will be randomly selected for review. Product types reviewed should include autologous and allogeneic inhouse collections of hematopoietic progenitor cells – apheresis and/or marrow.

<table>
<thead>
<tr>
<th>Patient Chart Date</th>
<th>Collect &amp; Receive Date/Time</th>
<th>Infectious Disease Markers</th>
<th>Apheresis Access</th>
<th>ABO</th>
<th>Sterility</th>
<th>Adverse Reaction to Infusion</th>
<th>Consumables/Equipment</th>
<th>Freezer Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Details of all “N” responses:
Donor Eligibility Deviations
October to December 2009

Ineligible Reasons Include:
• 20 = residence/travel for allogeneic donor (NMDP and sibling)
• 1 = donor with tattoo within 12 months
• 1 = auto confirmed positive Hep C
• 1 = sibling donor screened positive Hep C
• 1 = sibling donor with pending IDMs (drawn morning of collection)
• 1 = auto pending repeat IDMs for second priming
• 1 = incorrect letter was signed for use of Ineligible donor

Form Issue:
• 1 = incorrect letter was signed for use of Ineligible donor
# Donor Eligibility Audit

<table>
<thead>
<tr>
<th>Team</th>
<th>%On time/adequate</th>
<th>%late</th>
<th>%Signed before lab results</th>
<th># patients</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doc #1</td>
<td>80.00</td>
<td>0.00</td>
<td>20.00</td>
<td>5</td>
<td>Eligibility based on older labs. New labs reactive for Hep B core. Collection performed without confirmatory</td>
</tr>
<tr>
<td>Doc #2</td>
<td>66.67</td>
<td>33.33</td>
<td>0.00</td>
<td>3</td>
<td>On time forms signed same day of collection.</td>
</tr>
<tr>
<td>Doc #3</td>
<td>100.00</td>
<td>0.00</td>
<td>0.00</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Doc #4</td>
<td>0.00</td>
<td>0.00</td>
<td>100.00</td>
<td>3</td>
<td>For one of these patients form was re-signed before collection.</td>
</tr>
<tr>
<td>Doc #5</td>
<td>100.00</td>
<td>0.00</td>
<td>100.00</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Doc #6</td>
<td>0.00</td>
<td>0.00</td>
<td>100.00</td>
<td>1</td>
<td>Form was re-signed before collection.</td>
</tr>
</tbody>
</table>
Audit Results and Action

- Worked with BMT Nurse coordinators to determine what the reasons were for the <100% On Time/Adequate Forms.

- From this audit we discovered we were having challenges with our newly implemented in-house electronic ordering system for the infectious disease markers (IDM’s).

- Created a task force that consisted of a representative from the main laboratory, BMT nurse coordinator, apheresis supervisor, Cell Therapy QA staff member.
Audit Results and Action cont.

- A ‘one button’ order was created to ensure that all the correct IDM testing was done to include the correct donor test kits.
- We also changed to a testing lab that could produce the IDM test results in a 2-4 day turnaround.
- The changes helped the BMT nurse coordinators meet the requirement easier and closer to the 100% On Time/Adequate Eligibility forms prior to collection.
Labeling Citations in Apheresis Collection Inspections

- Label content must follow Appendices I and II
  - Ensure applicable SOPs meet the requirements
    - Audit the labeling procedure against the tables
    - Create forms and templates based upon the tables
    - Adequately train personnel on the procedure
  - Be sure label information matches actual practices
    - Example: Recommended storage temperatures should match storage temperatures in use by the facility
- Use ISBT 128 as a resource
  - Proper names are required
  - Templates can be useful
Labeling citations are common in apheresis collection facilities, and this is mostly due to improper label content. The label content must follow the Appendices I and II in the back of the Standards. Be sure to know those tables well, and make sure the applicable SOPs meet the requirements. Audit the SOP against the tables. You can create forms and templates based upon the tables as an added measure of certainty your labels will comply. Most importantly, adequately train personnel on the procedure. Inspectors have found that a combination of incomplete procedures and poorly trained personnel have resulted in issues with label content.

Be sure the information on the label matches actual practices. For example, storage information is often cited. The recommended storage temperature indicated on the label should match the storage temperatures in use by the facility.

Finally, use ISBT 128 as a resource. FACT does not currently require full implementation of the ISBT 128 database and technology; however, the use of ISBT 128 proper names is required. ISBT 128 templates, though not required, can be useful if you would like help with fitting all of the information on a single label.
Finally you have a QMP

- After you have developed the QMP take one patient thru it to ensure that it will work
- Participate in your programs Quality Management Meetings
- Present your audit findings
- Continue to improve your Quality Management Plan always!
Acknowledgements

- Dr. William Janssen, Director
- QA Staff at Moffitt Cancer Center
  - Martha Hackett
  - Jacklyn Stentz
- FACT