



**SARAH CANNON**

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**Tulane**  
Medical Center

**IDENTIFICATION OF APHERESIS STAFF  
HIRING & TRAINING NEEDS TO IMPROVE  
COLLECTION CORRELATION, PRODUCT  
QUALITY & PATIENT SAFETY**

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# BACKGROUND

**FACT standard C3.4.1 requires the number of trained collection personnel be adequate for the number of procedures performed.**

**FACT standard C4.4 requires the Quality Management (QM) Plan include Standard Operating Procedures (SOPs) addressing personnel/staff requirements for the Apheresis Collection Facility as evidenced by training, initial and continued competency records and Continuing Education. The Tulane Medical Center (TMC) Blood & Marrow Transplant QM Plan aligns with this standard.**

**At TMC, initial training of Apheresis personnel is provided jointly by contracted vendors and TMC. Training included review of TMC and vendor SOPs and BMT program specific SOPs which align with FACT standards.**

**Initial and continued competency (FACT standard C4.4.2.5) may be assessed by:**

- **observation**
- **written testing**
- **proficiency surveys**
- **review of collection procedure end-points**
- **other means as determined by said facility**

# BACKGROUND: TRIGGER EVENTS

## 2015 Mid-Quarter 2

- 50% of experienced HCT collection Apheresis staff turnover
- 2 new contract staff added to Apheresis

## 2015 End of Quarter 2

- 4 new contract staff added to Apheresis
- 50% (2) trained in HCT collection
- Turnover of the remaining 50% of experienced HCT Collection Apheresis staff
- 2 Apheresis staff newly trained in HCT collection remained
- TMC Blood/Marrow Stem Cell Transplant Program CD34+ Apheresis collection correlation dropped from 92% to 87%

## 2015 Quarter 3

- CD34+ Apheresis collection correlation dropped further to 78%

# OBJECTIVE

**Process and Performance Improvement (PPI) goal was to employ a sufficient number of well-trained staff, competent and proficient in HCT collections to:**

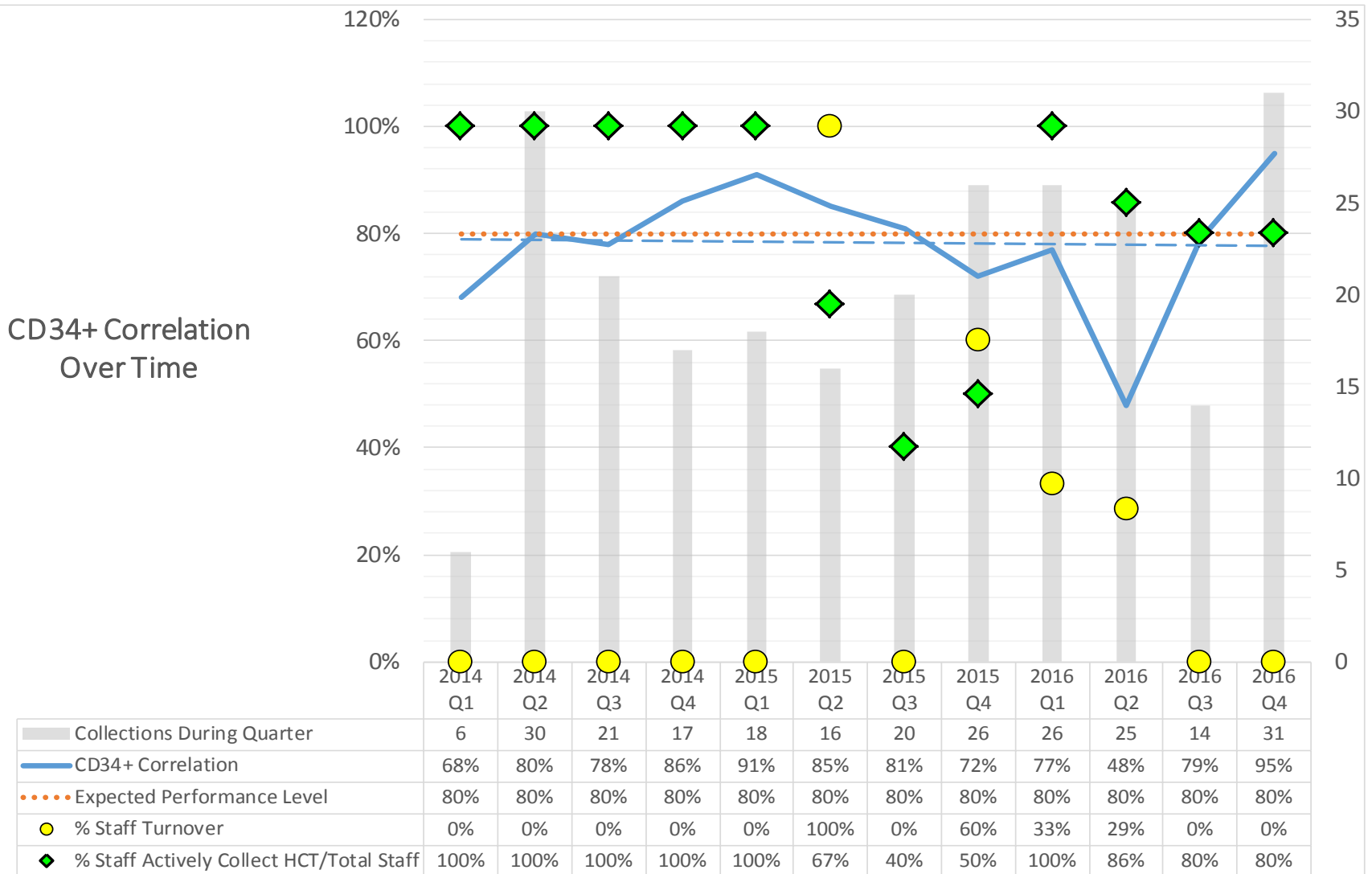
- **Safeguard patient safety**
- **Afford accurate collection data for successful validation of newly acquired machines**
- **Improve CD34+ collection correlation**
- **Afford assurance of high quality product for transplantation**

## At onset of 2015 Q3, BMT Quality Coordinator intervened to:

- Evaluate for potential process and performance improvements
- Assess that the contract vendors provided well-trained staff, competent and proficient in collections
- Analyze 100% of CD34+ collection data (n=161) over 21 months
  - Retrospective and concurrent data were collected from HCT patient (n=73) collections when both pre-collection peripheral and post-collection product absolute CD34+ counts were performed
  - Standard Pearson correlation coefficient analysis, measuring the strength of the association between the pre-collection peripheral and post-collection product absolute CD34+ was performed each quarter to evaluate if  $\geq 80\%$  expected performance level (EPL) was achieved
  - Number and root cause(s) for collections resulting in  $<80\%$  EPL were compared with the timing of apheresis collection staff hire and training/retraining interventions
  - Number and root cause(s) for failed or interrupted collections were compared with timing of apheresis collection staff hire and training/retraining interventions
- Report results of process and performance improvement project to the BMT Quality Management Committee at least quarterly

## Training and Retraining:

- TMC was able to engage the cooperation of the contracted vendors with process and performance improvement
- Rigorous staff training/retraining was provided for the contract vendor apheresis staff upon hire, every 2 months for 6 months, and then monthly for 4 months



Final/Revised  
CD34+ Collection  
Data following 21  
Month  
Retrospective  
Audit (2015 Q2 –  
2016 Q4)

(P) Absolute CD34+/uL Correlation to (A) Absolute

<b>Correlation</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
<b>Qtr 1</b>	0.6849	0.906026	0.768134	
<b>Qtr 2</b>	0.804115	0.85166	0.475601	
<b>Qtr 3</b>	0.782726	0.810027	0.786738	
<b>Qtr 4</b>	0.863877	0.71808	0.954229	

(P) Absolute CD34+/uL

<b>Average</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
<b>Qtr 1</b>	48.57	59.73	84.64	
<b>Qtr 2</b>	40.07	49.13	67.05	
<b>Qtr 3</b>	53.67	53.05	53.93	
<b>Qtr 4</b>	36.73	45.77	43.23	

(A) Absolute CD34+/uL

<b>Average</b>	<b>2014.00</b>	<b>2015.00</b>	<b>2016.00</b>	<b>2017.00</b>
<b>Qtr 1</b>	1338.00	1574.09	1157.11	
<b>Qtr 2</b>	1030.89	1448.67	829.25	
<b>Qtr 3</b>	1085.86	1242.55	1037.21	
<b>Qtr 4</b>	646.36	948.82	876.97	



# RESULTS:

## As of 2016 Q4:

- Six (6) contract vendor apheresis staff were trained to independent competency in HCT collections. Two (2) of these staff also completed advanced “trouble shooting” training. One (1) of the staff, although trained, is not performing HCT collections in order to manage personnel, monitor and audit HCT processes and procedures.
- The CD34+ collection correlation continued a downtrend for 3 quarters [2015 Q4: 72%, 2016 Q1: 77%, 2016 Q2: 48%] with 4.7% collection failure rate.
- CD34+ collection correlation improved:
  - Recent analyses of CD34+ collection correlation demonstrate quarterly improvement [2016 Q3: 79% and 2016 Q4: 95%] with 0% collection failure rate.
- Accurate collection data became available for successful validation of newly acquired machines.
- TMC was assured of high quality product for transplantation, e.g. optimal post-collection product absolute CD34+ was obtained.

# CONCLUSION:

**FACT standard C4.4 requires that the Quality Management Plan include SOPs addressing personnel/staff requirements for the Apheresis Collection Facility as evidenced by training, initial and continued competency records and Continuing Education. The TMC BMT QM Plan aligns with this standard.**

**Emphasizing TMC FACT Accreditation needs as reflected in its Quality Management Plan and SOPs, TMC was able to engage the cooperation of the contracted vendors for PPI.**

**Continuous monitoring of collection data as well as staff hiring and training patterns was essential to making significant improvements in TMC apheresis collection correlations, product quality and patient safety.**

# REFERENCES

1. **FACT-JACIE International Standards Accreditation Manual, Sixth Edition**
2. **<https://statistics.laerd.com/statistical-guides/pearson-correlation-coefficient-statistical-guide.php>**

# CONFLICT OF INTEREST DISCLOSURES

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**Incyte, Celgene, Astellas, Sanofi**

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**Thank you**