MNC COLLECTIONS USING Fenwal Amicus®:
A YEAR OF LEARNING

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Paula Loeffler RN, BSN, OCN
I do not have any relevant financial relationships with commercial interests that pertain to the content of my presentation.
Helpful Colleagues:

- Lizette Caballero, MLS(ASCP)CM
- Brenda Strzempekowski-Brun, RN, BSN, Med
About our Program

• Hospital-based, medium size (200+ transplant) adult program

• Approximate 300 (autologous + allogeneic) collections in 2014 (inpatient and outpatient units)

• Approximately 238 (auto + allo) collections in 2015 (163 collected in outpatient setting)
About our Center

• Heme/Onc/BMT Outpatient Infusion Center
• Treat on average 80-100 patients per day
• Provide infusion needs for outside clinics
• Transitioning MNC collections from inpatient to outpatient
• Outpatient program doing MNC only
• Minimum of 2 Apheresis RNs per shift
• Average 2-4 Apheresis patients per week
Types of Collections

- MNC collections: Auto and Allo

- CD34 cell dose goals:
  
  Multiple Myeloma: $8 \times 10^6$/kg *most common collections
  
  NHL, AML: $5 \times 10^6$/kg
  
  - Access: Peripheral veins and Central Venous Catheters
Background Information

• Until November 2014 all MNC collections performed using COBE® Spectra in hospital Apheresis/Hemodialysis Unit

• Goal: Transition majority of MNC collections to outpatient setting

• Preparations:
  - Select and purchase instrument
  - Select and train nursing staff
Instrument Selection

- We decided to test the two instruments commercially available to replace COBE: Amicus and Optia
- Stakeholders involved in the final decision:
  - Collection Facility Medical Director
  - Collection Facility Manager and Assistant Manager
  - Processing Facility Medical Director
  - Processing Facility Supervisor
- Meeting Organization:
  - Stakeholders met with each company (different dates)
  - The companies agreed to supply:
    - Instrument
    - Kits
    - Education Specialist
Outcome

- Optia continues to deplete donor’s platelet (PLT) count as much as Spectra. Amicus is more PLT sparing.
  - High PLT contamination may cause clumping in product and donors may require PLT transfusion.

- Amicus RBC contamination was higher than Optia.
  - May be a problem for ABO incompatible products

- Granulocyte contamination was as high with Optia as Spectra and much lower with Amicus products.
  - Granulocyte contamination is linked to lower post-thaw TNC viability and clumping during infusion.
What we learned

- **Parameters that may change ‘forever’:**
  - Collection Hours- more hours (5-5.5 hours)
    - Both instruments work under the principle of cycles and the higher the WBC the more cycles will require to collect
      - Point to Consider: collecting based on timing. Collect for 4 hours instead of blood volume or liters to be processed
      - Are we cutting ourselves short? Will shorter time add more days of collection?
  - Product Volume
    - Based on our experience during the testing phase, Optia collects more volume (up to 500ml) compared to Amicus (approx. 250ml). This impacts storage space.
Final Decision

- The decision was made to choose Amicus:
  - Based on the following parameters:
    - Smaller product volume
    - Lower granulocyte contamination
    - Platelet sparing capabilities of the instrument
    - Support and Availability of Fresenius Kabi representatives during transition to Fenwal Amicus Instrument
    - Responses from survey sent to institutions currently using Optia and/or Amicus
Amicus Process

Amicus Installation & Training
- Instrument install
- Product training
- SOP Development

Data Review after ~ 10 Procedures
- Checking to ensure products meet targets
- Make any necessary changes to settings

On-going support
- Increasing operator comfort level
- Changing offsets
- Answer lingering questions

Data Review after 30-40 collections
- Data comparison with predicate device
- Define next steps and future goals
Implementation Support and Training

- Amicus Training by Fresenius-Kabi Clinical Specialist
- Apheresis Cont. Education
- Moral Support from Transfusion Management
- FACT Training by our BMT Program
- Orientation to BMT Coordinator Role
Learning Amicus

- Trained over 2 weeks in Practice and Clinical Setting
  - Training by Fresenius-Kabi Clinical Specialist
- Day 1 – Load and Unload the Kit, over and over…
  - Reassurance on Day 1
- Training focused on:
  - Describing Process of MNC Collection
  - Learning Functions of Amicus Separator
  - Trouble Shooting Alarms
  - Defining Maintenance Schedule
  - Guidance in Creating our Procedural Flow Sheet and Departmental SOPs
Development of SOP

- Adapted UCSF Inpatient SOP
- Worked Closely with FK Clinical Specialist over 2 weeks to tailor SOP to Amicus
- Reviewed Current SOPs from Other Institutions
Working with Amicus

- Amicus is an automated machine but nursing manipulation is still key for harvest optimization

- Monitoring the RBC offset every cycle

- Feel strong sense of ownership with each collection

- Secondary validation in real time to fine tune collections for the next day if necessary

*Good Communication with BMT lab is essential
Tremendous Support from Fresenius-Kabi

- **Hotline Support**
  - 24/7 coverage of any issues centered around patient treatment

- **Clinical Specialist**
  - In touch on frequent basis for questions or curiosities

- **Technical Service Engineer**
  - Real time service
  - Been called to the rescue a few times during our learning curve
What We Like About Amicus

- User Friendly
- Alarms are easy to manage while troubleshooting
- 2 Air Traps manage air in the kit well
- Operator errors can be managed fairly easily
- Above mentioned 1-800 phone support
- No platelet transfusions prior to line removal
- Lower product volume
Adapting Amicus fit to UCSF’s Workflow

- Increase whole blood volume processed by manipulating cycle volumes, flow rates, AC ratios

- High volume of autologous collections with goal of 8 million CD34. This was a factor when developing our guidelines.

- Current order to process: 18 liters, 4x total blood volume, not to exceed 330 minutes.
Helpful resources

- **Literature review**: many informative articles focusing on Fenwal Amicus
  - Manual color monitoring to optimize HPC collections, JCA 2011
  - HPC collections, effects of increasing cycle volume on CE, Transfusion and Apheresis Science 2013
  - Comparison HPC collections Spectra vs. Amicus on pts. With Amyloidosis
  - Comparative evaluation of leukapheresis technology on unstimulated donors, VoxSanguinis 2013

- **Constant communication with Fresenius Kabi Clinical Specialists**

- **Peer to peer outreach at conferences and through email**

- **Constant review and evaluation of collection data by nursing staff, BMT lab, and Fresenius Kabi**
What We’ve Learned:

- Running larger cycle volumes up to 1400ml even when WBC >35k allows you to process more whole blood and improves chances of reaching cell dose goal in fewer number of collections.

- Collection rates kept at maximum of 80ml/min allows more whole blood to be processed in 5-5.5 hours. (higher rates not possible with peripheral access or with lower weight patients due to citrate intolerance)

- Adjustments can be made to optimize collection efficiency based on individual patient parameters.

- There will always be a few unpredictable occurrences due to many variables involved.
The first product collected in our unit
Looking forward to another year of learning.