

Implementing InterSol® Platelet Additive Solution

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Background

- ❑ The FDA granted 510(k) clearance to Fenwal, Inc for InterSol[®], a platelet additive solution (PAS) for use with Amicus Devices in the U.S. in December 2009
- ❑ PAS replaces about 65% of the plasma in single donor platelets
- ❑ American Red Cross Regions, North Central, St. Paul, MN and Heart of America, Peoria, IL participated in an operational trial to test Amicus 3.2 software and the collection of PAS platelets
- ❑ The American Red Cross became the first blood collection agency in North America to collect, manufacture, and supply PAS platelets on a routine basis. The impact of this implementation posed operational challenges and provided a foundation of knowledge for future

- ❑ Prior to the Op trial a Feasibility Study was conducted to determine compatibility with equipment and testing procedures
- ❑ Equipment tested
 - ❑ Sysmex XE-2100D hematology analyzer
 - ❑ Horiba ABX Micros 60 hematology analyzer
 - ❑ Orion pH meter with Accu-Phast electrode
 - ❑ bioMerieux BacT/Alert
- ❑ Testing Procedures
 - ❑ Immucor Capture-P

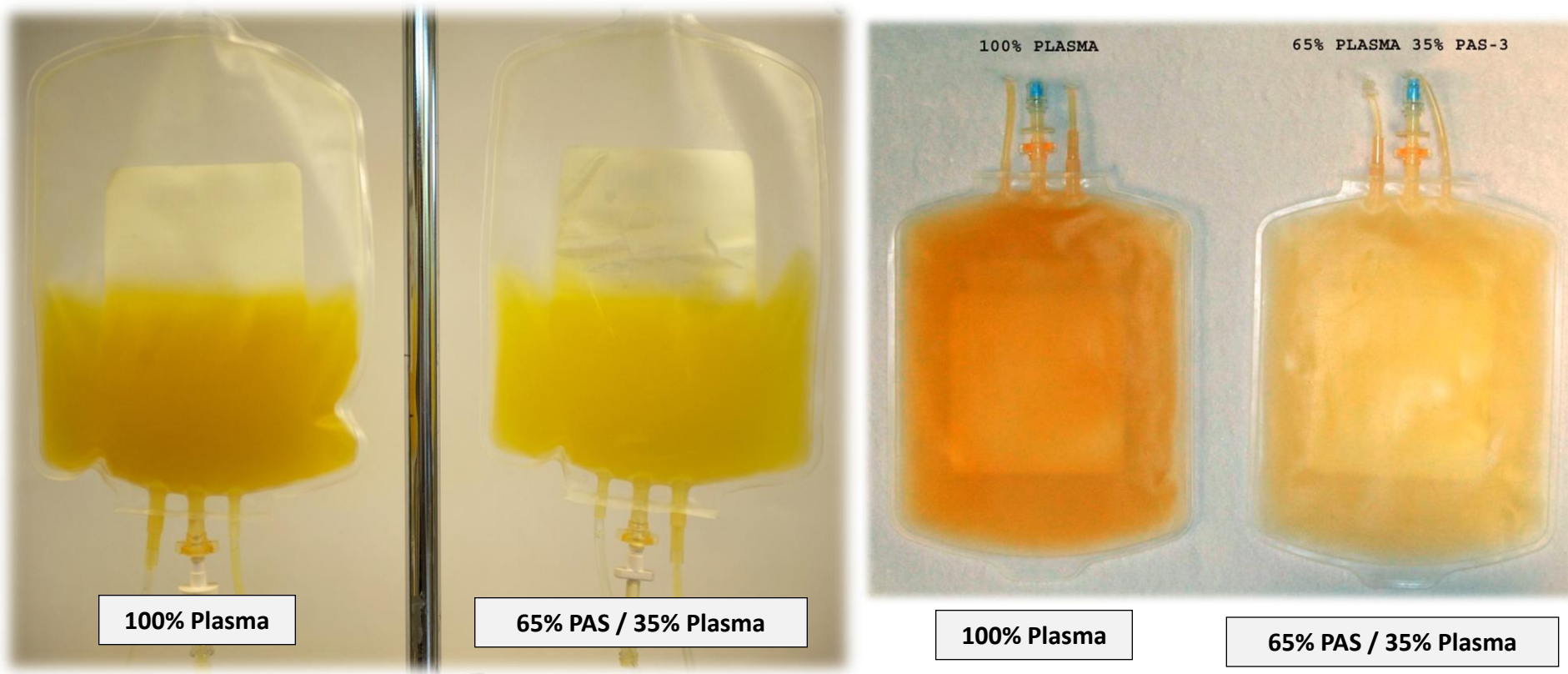
- ❑ Preparing for the Operational Trial
 - ❑ Assemble the project team
 - ❑ Project lead from each department
 - ❑ Develop an implementation protocol
 - ❑ Identify all procedures and forms impacted
 - ❑ Collections, Product Quality Control, and Product Manufacturing
 - ❑ Develop training and implementation schedule
 - ❑ Upgrade Amicus devices with the 3.2 software with PAS multiplier enabled
 - ❑ Training materials and schedule

Methods

- ❑ FDA language describing PAS platelets was added to the Circular of Information
- ❑ New product codes were entered into Red Cross and hospital customer systems
- ❑ IQ, OQ, and PQ was performed on all Amicus Devices
- ❑ Product codes for ARC and hospitals
- ❑ Pictures of PAS and 100% plasma platelets were provided to show a possible difference in appearance

Methods

Platelets in 65% PAS may appear slightly lighter in color than platelets in 100% plasma.

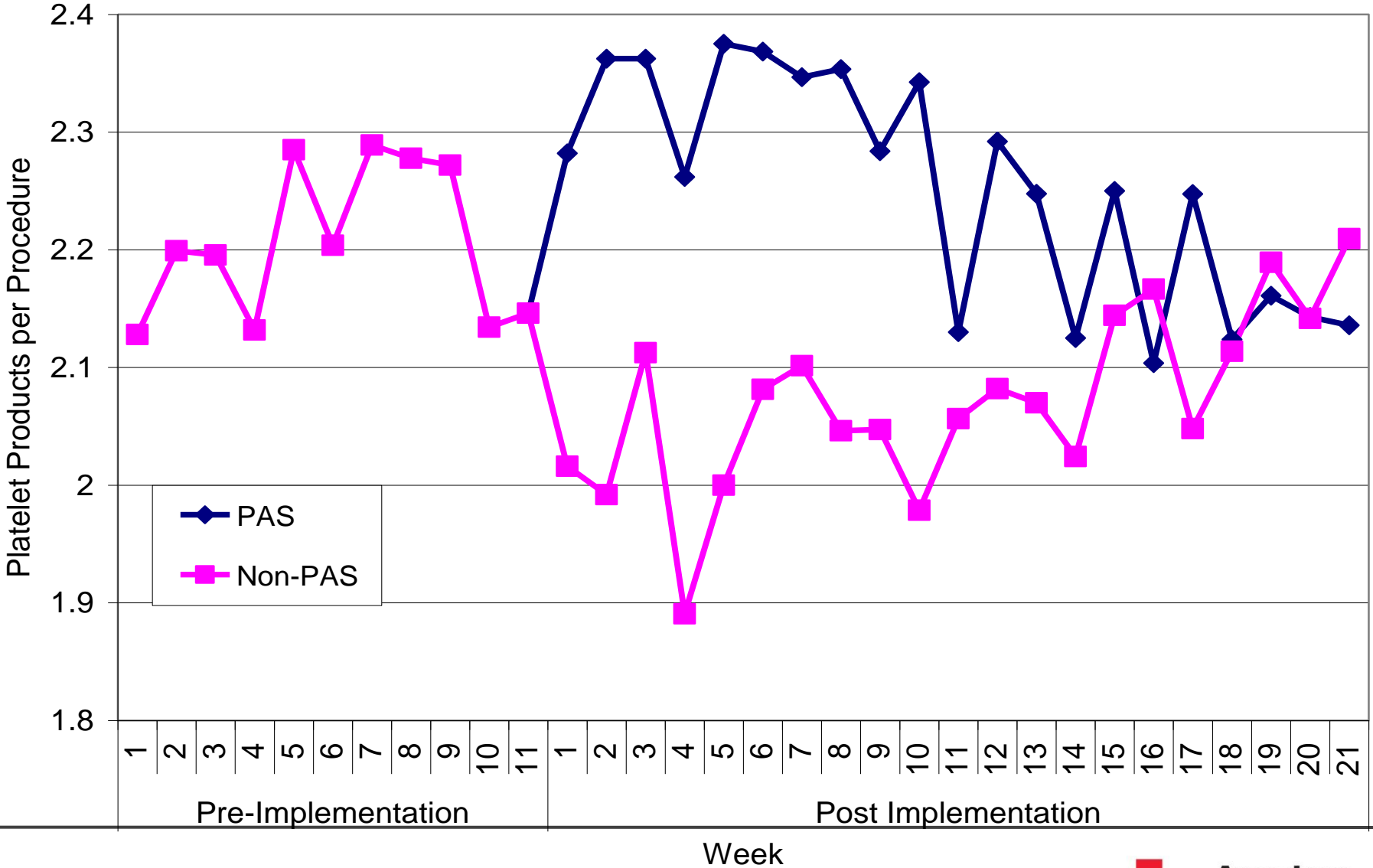


- ❑ PAS platelets performed no differently than platelets stored in 100% plasma using the Sysmex and Horiba ABX hematology analyzers, pH meter, BacT/Alert, and Capture-P Assay
- ❑ However with the Siemens Advia 120 hematology analyzer
 - ❑ There was a >10% difference in the platelet counts and an increase in yield failures other than samples held in the cold for 4 hours on Day 0 or Day 1
 - ❑ Since this region uses the Advia 120 workflow was changed to accommodate the 4 hour cold requirement

Results

- ❑ Four hours of training was required
- ❑ The collection process remained the same
- ❑ Device operators reported minor screen changes made the software upgrade more user friendly and efficient
- ❑ During procedure setup the operator selects the type of storage fluid
- ❑ PAS is added during the product transfer after the donor is disconnected
- ❑ Amicus automatically transfers the appropriate plasma and PAS to maintain a mix of 65% Intersol[®]/35% plasma Upgrade
- ❑ The platelet yield adjuster was recalibrated to the facilities hematology analyzer

Results



Results

SDP Procedures	Pre-Implementation % Concurrent Plasma Collected	Post Implementation % Concurrent Plasma Collected
Single	32.4%	44.8%
Double	29.6%	44.0%
Triple	0%	49.0%
Total	30.4%	46.2%

Conclusions

- ❑ Amicus software version 3.2 with the PAS option was successfully implemented
- ❑ The North Central Region became proficient at collecting PAS platelets within 4 months
- ❑ A new process was developed to allow for the use of the Advia analyzer to accurately count platelets
- ❑ The platelet yield adjuster was calibrated to help ensure that the final product yield was aligned with the programmed target yield
- ❑ Plasma for transfusion increased by 46%