What are Platelets?

- Platelets are colorless, irregularly shaped bodies found in blood.
- The primary role of platelets is to prevent bleeding in injured blood vessel walls by forming an aggregate at the site of injury.
- Platelets can also participate in blood coagulation, inflammation and wound healing.
What is an Apheresis Donation?

- Apheresis involves the use of machines to selectively collect a blood component (red cells, platelets, white cells or plasma).
- A specific blood component is selected and is automatically separated by the machine (most commonly platelets or plasma).
- The components that are not required are returned to the donor.
- The advantage of an apheresis donation is that relatively large amounts of the component can be selectively collected.
Who can Donate Blood

Age: 17th – 71st birthday (regular donor)
      17th – 61st birthday (first time donor)

Weight: At least 50 kg (110 lbs)

Hemoglobin: Must meet requirements

Frequency of Donation: Minimum interval between donations is 56 days

Health: In good health and feeling well.

Screening: At time of donation, a number of questions are asked to determine donor eligibility, e.g.:

* If donor has had a
  * Dentist visit: Donor must wait before donating for 3 days after visit
  * Cold, flu or sore throat: Full recovery
  * Ear/ body piercing or tattooing: 6 months
Why are Single Donor Apheresis Products Requested?

**Platelets:**
- To prevent alloimmunization (e.g., bone marrow transplantation).
- For refractory patients, HLA/platelet antigen matched for patients with specific HLA/platelet antibodies.
- For directed donations, e.g., mother to baby for neonatal thrombocytopenia (NTP).
Principles of apheresis

Anticoagulant added

Remaining blood components recombined and returned

Whole Blood (vein)

Blood components separated by centrifugation and selectively removed

Plasma
Platelets
Lymphocytes
Granulocytes
Erythrocytes
APHERESIS PROCEDURES - GENERAL

- Used for treatment or blood component donation
- Allows blood separation at bedside
- < 15% of blood volume in extracorporeal circuit
- Sterile, single use tubing and separation kit
- Anticoagulant must be added - usually citrate (ACD)
Apheresis Methods

- **Filtration**
  - Plasma only
  - Europe and Japan
  - Specialized U.S. procedures
  - Smaller equipment, smaller extracorporeal volume

- **Centrifugation**
  - Most versatile
  - Any cell or plasma can be removed
  - Popular in U.S.
  - Larger equipment and larger extracorporeal volume
APHERESIS TECHNOLOGY (centrifugal)

- **Continuous flow**
  - One or two access points
  - Continuous blood separation

- **Intermittent flow**
  - One access needed
  - Blood separation in cycles
  - Slightly longer processing time
  - Slightly larger extracorporeal volume
DONOR APHERESIS
APHERESIS DONOR COLLECTIONS

- Platelets
- Plasma
- Granulocytes
- Red blood cells
- Lymphocytes
- Peripheral blood stem cells
Donor Apheresis

- Advantages
  - Select only component(s) needed
  - Return rest of blood
  - No need for component separation in lab
  - More frequent donation allowed (some)

- Disadvantages
  - Expense/equipment/training
  - Citrate exposure
Donor Apheresis

- Probable trend in future
- May totally replace whole blood donation
- Can customize collection:
  - Individual donor preferences
  - Blood type of donor
  - Inventory needs of blood center
DONOR APHERESIS EQUIPMENT - U.S., 2002

- Continuous Flow
  - Baxter/Fenwal CS-3000 Plus, Amicus
  - Gambro/Cobe Spectra, Trima

- Intermittent Flow
  - Haemonetics LN-8150 MCS, LN-9000 MCS
Automated Blood Component Collection System

2 - 3 Transfusions

- Packed RBC 0-2 Tx
- Plasma 0-3 Tx @ 200ml
- Platelet 0-3 Tx
COMPLICATIONS - DONOR APHERESIS

- **Common**
  - Citrate toxicity
  - Hematoma or infiltration

- **Rare**
  - Allergy (citrate, plasticizer)
  - Cellulitis
  - Thrombosis
  - Change in volume status
CITRATE

- Chelates calcium
- Metabolized in liver, kidney and skeletal muscle
- Cleared quickly from circulation
- Administered as ACD
SIGN/SYMPTOMS OF CITRATE TOXICITY

- Tingling/numbness around nose and mouth "circumoral parasthesias"
- More extensive tingling
- Muscle cramping
- Vibration in chest
- Nausea
- Tetany
- Chvostek's sign
TREATMENT - CITRATE TOXICITY

- **Mild cases:**
  - Tums
  - Milk
  - Slow procedure
  - Decrease ratio of anticoagulant to blood

- **No bleeding tendency**

- **Much anticoagulant removed in platelet collection**

- **Severe cases -- IV calcium replacement**
PLATELET APHERESIS
Available Platelet Preparations

- Whole Blood Derived (e.g. Pooled)
- Apheresis (Single Donor)
  - Community Donor (RAP)
  - Family Donor
  - HLA Matched Donor

For illustration see below.
Whole Blood 500 mL

PRP
PRBC 1-6°C

Platelets 20-24°C

PRP

PRP

FFP -18°C

CPP -18°C

Cryo -18°C

250 mL

50 mL

15 mL

200 mL

50 mL

Soft Spin

Hard Spin

Thawed at 4°C
DONOR ELIGIBILITY - PLATELET APHERESIS

- No whole blood donation for 8 weeks
- No platelet donation for 48 hours
- No aspirin in last 36 hours
- Platelet count >150,000/ul
- No more than 2 times per week
- No more than 24 donations in one year
PLATELET COUNT-PLATELET Apheresis

- Platelet count drops 25-35% after procedure
- Rarely below 90,000
- No bleeding complications
- Recovers in several days
APHERESIS QUALITY CONTROL

- **Platelets:**
  - $\geq 3.0 \times 10^9$ platelets per collection (90%)
  - pH $\geq 6.2$ at 5 days (90%)
  - May check at issue if none available at 5 days
  - Test at least 4 per month:
    - Site, manufacturer, split vs single

- **Granulocytes:**
  - $\geq 1.0 \times 10^{10}$ WBCs per collection (75%)
SPLIT APHERESIS PLATELETS

- Donor with high platelet count
- Slightly longer procedure
- Yields bag of equal to or greater than $6.5 \times 10^9$ platelets
- Split immediately into two or three "doses"
PLATELET UNIT COUNTING

- QC for count and pH (4 per month)
- Also must count every bag
- Not required to label bag with count
- Low count bags must be so labeled
LEUKOREDUCTION AND PLATELET APHERESIS

- Gambro/Cobe - LRS system for Spectra and Trima
- Fenwal - Amicus with elutriation
- Haemonetics - Filter in MCS kit
ADVANTAGES – LEUKOREDUCTION IN APHERESIS

- Leukoreduction prior to storage
- No filter failure
- No loss of cells in filter
- Possible cost advantage
CONTAMINATION LEUKOCYTE LEVEL - QUALITY CONTROL

- WBCs < 5.0x10^9 routinely
- WBCs < 5.0x10^6 to be "leukoreduced"
- Europe and proposed U.S. 1.0 X 10^6
- Must count 4 per month per each site and technology (singles, doubles, and triples)
APHERESIS COMPONENTS WITH SAME NUMBER

- Double RBC collections
- Double platelet collections
- Aliquots of jumbo plasma
TO YOUR APHERESIS PROGRAM.

For detailed information describing intended use, warnings, precautions and contraindications, refer to the instructions provided for each device or contact Haemonetics Corporation.

HAEMONETICS®
Apheresis Procedure Length

- Red cells plus plasma -- 40 minutes
- Double red blood cells -- 45 minutes
- Platelets (single) -- 70 to 120 minutes
- Granulocytes -- 3 hours
- Peripheral blood stem cells -- 4 to 6+ hours
Platelets Pheresis

- Hemapheresis is used to harvest a therapeutic adult dose of platelets from one individual donor
- Contains $> 3 \times 10^{11}$ platelets
- Equivalent of 6-8 units of platelets
- Leukocytes reduced
PLATELET PACKS: SINGLE DONOR

- Indications
  - Thrombocytopenia (<50,000/microL)
  - Cancer patients having chemo. or radiation (<20,000)
  - DIC (<50,000)
  - Massive transfusion (<50,000)
- If patient becomes refractory to plts (has plt Abs), will need to give single donor packs (plateletpheresis units)
  - determine 1 hr post transfusion plt increment (see p. 347)
  - if less than 50% of expected two times, pt. considered refractory
- ABO/Rh compatible
PLATELET PACKS: SINGLE DONOR

- Processing - requires special equipment to perform apheresis procedure
- At least $3 \times 10^{11}$ plts in 300 mL
- Storage at RT with constant agitation for 5 days
- Indications - same as for random donor packs but patient has been shown to be refractory
- Expected net gain - 30,000 to 60,000/microL
- ABO/Rh compatible; may also type to determine HLA compatibility
Haemoglobin Testing
Bacterial Detection of Platelet Products

- AABB requirement since 3/04
- Two commercial systems detecting
  - CO₂ generation
  - O₂ consumption
- Swirling or pH
Documentation
Maintenance
Calibration
Labeling
of Platelet
DOCUMENTATION

Documents

- approved information that describes the organisation’s quality system policies, processes and procedures
- mostly SOPs eg. PLT preparation

Records

- capturing process/ procedure data on forms eg. PLT log
Quality System
Documentation Heirarchy

I  POLICY DOCUMENTS  
   what will be done

II  PROCESS DESCRIPTION DOCUMENTS  
   how it happens

III  PROCEDURE DOCUMENTS  
    how to do it

IV  RECORDS  
    what was done
Documentation

Component preparation

General rules remain

Blood collection
  - type of bags

- Time
  - collection time
  - bet’ collection and separation
  - time of storage

Separation
  - centrifuge
  - centrifugation time and speed
### Platelet concentrate (RDP) Quality Control

**Facility Name**

Date ___________

<table>
<thead>
<tr>
<th>Centrifuge #</th>
<th>Donor #</th>
<th>Expiration date</th>
<th>Volume 40-60 ml</th>
<th>pH &gt; 6.2</th>
<th>Platelet count</th>
<th>Total plts per unit &gt;5.5 x10^{10}</th>
<th>Results Acceptable? Yes/No</th>
<th>Date tested</th>
<th>Tech</th>
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#### Total % units meeting requirements

- pH __ (100%)
- Volume __ (100%)
- Plt count __ (>75%)

**Comments** __________________________________________________________

Reviewed by ___________ Date ___________  

SOP/ version date
MAINTENANCE

Equipment maintenance

- Documentation of installation
- Installation validation
- Preventive maintenance - AMC
- Regular calibration, and after repairs
- Performance monitoring
RECORDS OF
EQUIPMENT MAINTENANCE

- Instrument serial # ___________________
- Model no. ____________________________
- Date of purchase ___________________
- Name of supplier ____________________
- Maintenance visit schedule __________
- Dates of breakdown / repairs __________

Signature ____________________________
CALIBRATION

Establishment of accuracy over operating range by appropriate reference material/calibrators

All calibrated equipment label with
- date of last calibration and signature
- date of next calibration
CALIBRATION

PERFORMANCE CHECKS
To verify that instrument in specified range of accuracy and precision

REFERENCE STANDARDS
Measurement standards
- Certificate of assigned values
Traceable to national standard of measurement
- Precalibrated certified stds.
- Internal working std.
RECORDS OF CALIBRATION

- Instrument serial # ________________
- Date of calibration ________________
- Due date of next calibration __________
- Details of adjustment/repairs __________
- Results of calibration ________________
  before/after repairs ________________
- Statement of compliance _____________

Signature ________________
LABELING

Critical material in document management system

- Must conform to regulatory requirements
- Quality supervisors must review/approve before use
- Specific and controlled - size, type, wording
- Bar coded labels
  ISBT 128: information, wording, location standardized
  enhances efficacy, accuracy & safety
- Master set, careful when change out of old stock
- Special labeling e.g. irradiated or LD product