Donor Apheresis:
Products, Donors, Instrumentation, and Adverse Events

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Conflicts of Interest

- None
Objectives

- Donor apheresis products/characteristics
- Qualifications unique to apheresis donors
- Apheresis donor instrumentation
- Adverse events during apheresis donation
Donor Apheresis Products/Characteristics
Donor Apheresis Products/Characteristics

• Apheresis Red Blood Cells
  – LR vs. Not LR

• Apheresis Platelets
  – LR vs. Not LR

• Plasma

• Apheresis Granulocytes
Donor Apheresis Products/Characteristics

• Multiple components can be collected from a single apheresis donor session
  – PLT + plasma
  – RBC + Plasma
  – RBC + PLT
  – RBC + PLT + plasma
  – 2-RBC
Apheresis Red Blood Cells

- Average collection of $\geq 60$ g hemoglobin/unit
  - Or 180 mL RBCs/unit
- 95% of units sampled $>50$ g hemoglobin
  - Or 150 mL RBCs/unit
Apheresis Red Blood Cells
Leukocytes Reduced

- Average collection of $\geq 51$ g hemoglobin/unit
  - Or 153 mL RBCs/unit
- $<5 \times 10^6$ leukocytes/unit
- $>95\%$ of units sampled $>42.5$ g hemoglobin/unit
  - Or 128 mL RBCs/unit
Apheresis Platelets

• ≥90% of units sampled have
  – ≥3.0 x 10^{11} PLT
  – pH ≥ 6.2 at time of issue/end of storage

• For Apheresis Platelets Leukocytes Reduced
  – Same PLT count and pH thresholds
  – ≥95% of units sampled have < 5 x 10^6 leukocytes
Plasma

• Fresh frozen plasma (FFP)
  – Placed at $\leq -18$ C within 8 hours of collection

• Plasma frozen within 24 hours after phlebotomy (FP24)
  – Placed in refrigeration (1-6 C) within 8 hours of collection
  – Placed at $\leq -18$ C within 24 hours of collection
Apheresis Granulocytes

• Must contain $\geq 1.0 \times 10^{10}$ granulocytes/unit in $\geq 75\%$ units sampled

• To achieve this, additional agents must be used
  – Sedimenting agents
    • Hydroxyethyl starch induces RBC aggregation
    • Facilities must define and control the maximum amount of this used in a given time period due to side effects
      – Intravascular volume expansion
      – Severe pruritus $\rightarrow$ anaphylactoid reactions
      – Coagulopathy (via decreases of Factor VIII and vWF)
Apheresis Granulocytes

– Corticosteroids
  • Can increase circulating granulocytes by 200%
  • 60 mg prednisone p.o. vs. 8 mg dexamethasone p.o. administered 24 hours prior to collection
  • Donors with DM, cataracts, HTN, PUD - contraindicated

– Granulocyte colony stimulating factor (G-CSF)
  • Can increase circulating granulocytes by 500-1000%
  • 5-10 μg/kg administered 8-12 hours prior to collection

• With these strategies, potentially $1 \times 10^{11}$ or more granulocytes per collection can occur

Strauss RG et al, Vox Sang 2011.
Qualifications Unique to Apheresis Donors
Special Qualifications for Apheresis Donors

• Same as for whole blood...with a few exceptions
• Frequent plasmapheresis donor (source plasma)
  – More frequently than once every 4 weeks
    • At least 2 days apart, and ≤ 2x in any 7 days
  – Every donation tested for: HIV 1/2, Hepatitis B/C
  – Testing every 4 months for
    • Syphilis (Non-reactive)
    • Total plasma/serum protein (>6.0 g/dL)
    • SPEP or quantitative immunodiffusion assay (WNL)
    • Annual physical examination

21 CFR 610.40
21 CFR 640.65
Special Qualifications for Apheresis Donors

• Infrequent plasmapheresis donor (source plasma)
  – Less frequently than once every 4 weeks
  – Treated like a new donor every time
• Maximum plasma losses
  – 110-175 lbs → 12L/12 months
  – >175 lbs → 14.4L/12 months
• If no other components donated, malarial risk factors not a cause for deferral

21 CFR 640.63
Special Qualifications for Apheresis Donors

• 1-unit erythrocytapheresis ("single RBC unit")
  – 8 week donation interval

• 2-unit erythrocytapheresis ("double RBC unit")
  – 16 week donation interval
  – Hgb/Hct criteria dependent on
    • Donor gender
    • Specific apheresis instrument
    • Hct ≥ 40%
  – Donation will not drop Hgb/Hct <10 g/dL and 30%
Special Qualifications for Apheresis Donors

• Plateletpheresis donors may donate
  – Single, double, or triple product
  – 2x/week (at least 2 days apart)
  – 24x/year

• Start PLT ≥150,000/µL and End PLT ≥100,000/µL
  – Can be performed before starting collection, or
  – Use average of previous pre-procedure counts, or
  – Default count

  • If qualifying PLT count not determined prior, split product should not be collected from 1st-time donors
Special Qualifications for Apheresis Donors

- No aspirin or piroxicam within 48 hours
- No clopidogrel or ticlopidine within 14 days
- May donate if whole blood donated within 8 weeks AND extracorporeal volume of instrument <100 mL
- Plasma volume collected/collection
  - ≤500 mL if 110-175 lbs, or
  - ≤600 mL if >175 lbs, or
  - Per instrument specifications
Special Qualifications for Apheresis Donors

• Apheresis Granulocytes donation
  – Can usually donate no more than 8-12 times/12 month period
  – Not evidenced based restriction, and exceptions may be made
  – Donors often recruited from plateletpheresis donor pool or patient’s relatives/social network
  – ABO/D status is respected, but can be mismatched if medical need outweighs risk

# RBC Losses and Deferral

<table>
<thead>
<tr>
<th>1\textsuperscript{st} RBC Loss</th>
<th>2\textsuperscript{nd} RBC Loss Within 8 week period</th>
<th>Deferral</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\geq$ 300 mL</td>
<td>-</td>
<td>16 weeks</td>
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<tr>
<td>$&lt; 200$ mL</td>
<td>1\textsuperscript{st} + 2\textsuperscript{nd} losses total $\geq$ 300 mL</td>
<td>16 weeks</td>
</tr>
<tr>
<td>200-299 mL</td>
<td>-</td>
<td>8 weeks</td>
</tr>
<tr>
<td>$&lt; 200$ mL</td>
<td>1\textsuperscript{st} + 2\textsuperscript{nd} losses total = 200-299 mL</td>
<td>8 weeks</td>
</tr>
<tr>
<td>$&lt; 200$ mL</td>
<td>1\textsuperscript{st} + 2\textsuperscript{nd} losses total $&lt; 200$ mL</td>
<td>None</td>
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Apheresis Donor Instrumentation
# Apheresis Donor Instrumentation

<table>
<thead>
<tr>
<th>Instrument</th>
<th>GRAN</th>
<th>PLT</th>
<th>cRBC</th>
<th>2-RBC</th>
<th>PLASMA</th>
<th>cPLASMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenwal ALYX</td>
<td></td>
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<td>Fenwal Autopheresis C</td>
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<td>TerumoBCT Spectra Optia</td>
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<td><strong>TerumoBCT Trima V-4</strong></td>
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<td>Haemonetics Cymbal</td>
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<td><strong>Haemonetics MCS+ LN9000</strong></td>
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<td>Haemonetics PCS-2</td>
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</table>

cRBC=concurrent (1-unit) RBC; cPLASMA=concurrent plasma

Adverse Events During Apheresis Donation
Apheresis-Associated Adverse Events

• Many of these are similar to those seen with whole blood donations
• Some differences exist
  – Instrumentation used for collection
  – Frequency
### Incidence of tabulated adverse events

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Donor category</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First-time (2,295)</td>
<td>Repeat (17,303)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
<td>Number</td>
</tr>
<tr>
<td>Citrate effects</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Nausea and/or vomiting</td>
<td>20</td>
<td>0.87</td>
<td>46</td>
</tr>
<tr>
<td>Tetany or seizure</td>
<td>2</td>
<td>0.09</td>
<td>7</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>0</td>
<td>0.01</td>
<td>2</td>
</tr>
<tr>
<td>Vasovagal effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pallor and/or diaphoresis</td>
<td>43</td>
<td>1.87</td>
<td>55</td>
</tr>
<tr>
<td>Nausea and/or vomiting</td>
<td>20</td>
<td>0.87</td>
<td>23</td>
</tr>
<tr>
<td>Syncope and/or seizure</td>
<td>9</td>
<td>0.39</td>
<td>7</td>
</tr>
<tr>
<td>Pulse &lt;50</td>
<td>0</td>
<td>0.02</td>
<td>3</td>
</tr>
<tr>
<td>Pulse &gt;120</td>
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<td>0.02</td>
<td>3</td>
</tr>
<tr>
<td>Systolic blood pressure &lt;80</td>
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<td>0.02</td>
<td>3</td>
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<tr>
<td>Venipuncture</td>
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<tr>
<td>Severe pain</td>
<td>10</td>
<td>0.44</td>
<td>21</td>
</tr>
<tr>
<td>Nerve damage</td>
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<td>0.00</td>
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<tr>
<td>Palpable hematoma</td>
<td>48</td>
<td>2.09</td>
<td>176</td>
</tr>
</tbody>
</table>

## Incidence of tabulated adverse events

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>First-time (2,295)</th>
<th>Repeat (17,303)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
</tr>
<tr>
<td>Other severe events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chills and/or rigors</td>
<td>7</td>
<td>0.31</td>
</tr>
<tr>
<td>Arrhythmia (not citrate induced)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cardiopulmonary events</td>
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</tr>
<tr>
<td>Respiratory distress</td>
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<td>0</td>
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<tr>
<td>Circulatory collapse</td>
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<tr>
<td>Cardiac arrest</td>
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<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Malfunctions</td>
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<td></td>
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<tr>
<td>Hemolysis</td>
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<td>0.01</td>
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<tr>
<td>Air embolus</td>
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<td>0</td>
</tr>
<tr>
<td>Clot or leak</td>
<td>5</td>
<td>0.22</td>
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<tr>
<td>Inability to return blood</td>
<td>6</td>
<td>0.26</td>
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<tr>
<td>Donation procedure</td>
<td>Reactions</td>
<td>Number</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Platelet (n = 17,584*)</td>
<td></td>
<td>185</td>
</tr>
<tr>
<td>Granulocyte (n = 594*)</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Plasma (n = 1,359*)</td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>
Side Effects Within 4 Weeks After Granulocyte Donation

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