Objectives

• Discuss the action, indications, contraindications, dosage, expected effects, storage and quality control requirements for blood components

• Discuss the action, indications, contraindications, dosage and expected effects of blood derivatives
Blood Collection

1. Blood is drawn.
2. Blood is separated into components by a centrifuge.
3. Needed components are collected into sterile bags.
4. Unused components are returned to the donor.
# Anticoagulant-Preservative Solutions

<table>
<thead>
<tr>
<th>Anticoagulant</th>
<th>Content (mg in 63mL)</th>
<th>Shelf life (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACD-A</td>
<td>1386 mg Sodium citrate 504 mg Citric acid 1599 mg Dextrose</td>
<td>21</td>
</tr>
<tr>
<td>ACD-B</td>
<td>832 mg Sodium citrate 504 mg Citric acid 956 Dextrose</td>
<td>21</td>
</tr>
<tr>
<td>CPD</td>
<td>1660 mg Sodium citrate 206 mg Citric acid 1610 mg Dextrose 140 mg Monobasic sodium phosphate</td>
<td>21</td>
</tr>
<tr>
<td>CP2D</td>
<td>1660 mg Sodium citrate 206 mg Citric acid 3220 mg Dextrose 140 mg Monobasic sodium phosphate</td>
<td>21</td>
</tr>
<tr>
<td>CPDA-1</td>
<td>1660 mg Sodium citrate 206 mg Citric acid 2010 mg Dextrose 140 mg Monobasic sodium phosphate 17.3 mg Adenine</td>
<td>35</td>
</tr>
</tbody>
</table>
## RBC Additive Solutions

<table>
<thead>
<tr>
<th>Content</th>
<th>AS-1 (Adsol)</th>
<th>AS-3 (Nutricel)</th>
<th>AS-5 (Optisol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose 2200 mg/100mL</td>
<td>2200</td>
<td>1100</td>
<td>900</td>
</tr>
<tr>
<td>Adenine 27 mg/100mL</td>
<td>27</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Monobasic sodium phosphate</td>
<td>0</td>
<td>276</td>
<td>0</td>
</tr>
<tr>
<td>Mannitol 750 mg/100mL</td>
<td>750</td>
<td>0</td>
<td>525</td>
</tr>
<tr>
<td>Sodium chloride 900 mg/100mL</td>
<td>900</td>
<td>410</td>
<td>877</td>
</tr>
<tr>
<td>Sodium citrate 0 mg/100mL</td>
<td>0</td>
<td>588</td>
<td>0</td>
</tr>
<tr>
<td>Citric acid 0 mg/100mL</td>
<td>0</td>
<td>42</td>
<td>0</td>
</tr>
</tbody>
</table>

- Extends shelf-life to 42 days

Platelet Additive Solution 3

- Intersol™ solution
- Used in the storage of AMICUS-derived leukoreduced apheresis platelets
- Replaces 65% of plasma in platelets
- Each 100mL contains:
  - 305 mg Dibasic Sodium Phosphate, Anhydrous
  - 93 mg Monobasic Sodium Phosphate, Monohydrate
  - 318 mg Sodium Citrate, Dihydrate
  - 442 mg Sodium Acetate, Trihydrate
  - 452 mg Sodium Chloride
Platelet Additive Solution 3

- Decreases allergic transfusion reactions but not febrile nonhemolytic transfusion reactions

**TABLE 1. ATR incidence by type of AP transfused**

<table>
<thead>
<tr>
<th>APs transfused</th>
<th>ATRs</th>
<th>Transfusions</th>
<th>Incidence</th>
<th>RR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-PAS</td>
<td>72</td>
<td>3884</td>
<td>1.85%</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>PAS</td>
<td>12</td>
<td>1194</td>
<td>1.01%</td>
<td>0.54 (0.30-0.99)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**TABLE 2. FNHTR incidence by type of APs transfused**

<table>
<thead>
<tr>
<th>APs transfused</th>
<th>FNHTR</th>
<th>Transfusions</th>
<th>Incidence</th>
<th>RR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-PAS</td>
<td>27</td>
<td>3884</td>
<td>0.70%</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>PAS</td>
<td>7</td>
<td>1194</td>
<td>0.59%</td>
<td>0.84 (0.37-1.93)</td>
<td>0.69</td>
</tr>
</tbody>
</table>

Tobian et al. Transfusion. 2014 Jun;54(6):1523-9
Platelet Additive Solution 3

- Lower CCI within 4 hours of transfusion

<table>
<thead>
<tr>
<th></th>
<th>Non-PAS APs</th>
<th>PAS APs</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCI</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI)</td>
<td></td>
</tr>
<tr>
<td>1-4 hr</td>
<td>4932 (4452-5412)</td>
<td>3766 (3375-4158)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12-24 hr</td>
<td>2135 (1696-2573)</td>
<td>1745 (1272-2217)</td>
<td>0.14</td>
</tr>
</tbody>
</table>
Whole Blood

- Volume: 450 mL or 500 mL
- Collected into anticoagulant preservative solution (63 mL or 70 mL)
- Content: RBC, plasma, platelets, WBC
- Transfused units must be ABO identical with recipient

www.bing.com/images/search?q=whole+blood
Autologous Whole Blood

- Indication: patients requiring blood transfusions
- Donor-safety screening criteria available
- Units labeled: “FOR AUTOLOGOUS USE ONLY”
- 1st unit in 30 day period tested for infectious diseases if shipped to different facility for transfusion
- Units with reactive test result labeled “Biohazard”
- Infectious disease testing not required if collected and transfused in same facility
- Untested units labeled “DONOR UNTESTED”
- Storage: 1-6°C
Blood Component Separation (USA)

- Whole blood
  - Soft spin
    - Platelet-rich plasma
    - Packed red blood cells
  - Hard spin
    - Plasma
    - Platelets
  - Freeze, thaw, spin
    - Cryoprecipitate
    - Cryoprecipitate-reduced plasma
    - Plasma derivatives

Blood Component Separation (Outside USA)

- Whole blood
  - Hard spin
    - Plasma
    - Cryoprecipitate
    - Cryoprecipitate – reduced plasma
    - Plasma derivatives
    - White blood cells
    - Platelets
  - Soft spin
    - Buffy coat
    - Packed red blood cells

Packed Red Blood Cells (pRBCs)

- Source: Whole blood or apheresis collection
- Volume: 225 mL to 350 mL
- Hematocrit: 65%-80%

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org
pRBCs

• Action: increase oxygen carrying capacity

• Indications
  – Symptomatic anemia
  – Red cell exchange transfusion

• Contraindications
  – Anemias that can be corrected with iron, vitamin B₁₂, folic acid or EPO
  – Volume expansion
  – Increase oncotic pressure of blood

Circular of Information for the Use of Human Blood and Blood Components.
www.aabb.org
pRBCs

• Dosage and expected effect: 1 unit pRBCs = 1 g/dL (3%) increase in Hgb

• Administration
  – Pre-transfusion testing for ABO/Rh compatibility required
  – Transfuse slowly to detect onset of acute reactions
  – Transfuse within 4 hours

• Storage: 1-6°C for 21, 35 or 42 days

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org
### Quality Control

<table>
<thead>
<tr>
<th>Component</th>
<th>AABB</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red blood cells</td>
<td>RBC without additive solutions shall be prepared using a method known to result in a final hematocrit of ≤80%.</td>
<td>None</td>
</tr>
<tr>
<td>RBCs Leukocyte Reduced</td>
<td>Leukocyte-reduced blood and components shall be prepared by a method known to reduce the leukocyte number to &lt;5x10⁶ for RBCs in at least 95% of the units sampled and retain 85% of red cells after filtration.</td>
<td>Test 1% of all units from WB (with a minimum of 4 units/month) for each method of leukocyte reduction for residual leukocytes &lt;5 x 10⁶/unit.</td>
</tr>
<tr>
<td>Component</td>
<td>AABB</td>
<td>FDA</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Deglycerolized RBCs</td>
<td>Deglycerolized RBCs shall be prepared by a method known to ensure adequate removal of cryoprotective agents, result in minimal free hemoglobin in the supernatant solution, and yield a mean recovery of ≥80% of the preglycerolized red cells following the deglycerolization process.</td>
<td>None</td>
</tr>
<tr>
<td>Apheresis RBCs Leukocytes Reduced</td>
<td>Ensure a final component contains a mean hemoglobin of ≥51g (or 153 mL red cell volume) and &lt;5 x 10^6 residual leukocytes per unit. At least 95% of units sampled shall have &gt;42.5 g of hemoglobin (or 128 mL red cell volume).</td>
<td>Same as RBCs Leukocytes Reduced for residual leukocyte determination. Also test 1% of the units or minimum 50 units per month from each collection site for hemoglobin mass.</td>
</tr>
</tbody>
</table>
Plasma

- Source: Whole blood or apheresis collection
- Volume: 200-250 mL (up to 400-600 mL)
- Content: Albumin, coagulation factors, fibrinolytic proteins, immunoglobulin, other proteins

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org

www.bing.com/images/search?q=fresh +frozen+plasma
Plasma

• Classification
  – Fresh Frozen Plasma
  – Plasma frozen within 24 hours after phlebotomy
  – Plasma Cryoprecipitate Reduced
  – Liquid plasma
  – Thawed plasma

• QC requirement: None
Fresh Frozen Plasma (FFP)

- Separated and frozen at -18°C or colder within 8 hours of collection
- Action: Source of plasma proteins for individuals with deficiency of or defective plasma proteins
- Indications
  - Replacement of multiple plasma coagulation factors (eg liver disease, DIC)
  - Massive transfusion with significant coagulation deficiencies
  - Warfarin reversal

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FFP

• Indications
  – Transfusion or plasma exchange in TTP
  – Coagulation factor deficiencies, congenital or acquired, when no coagulation concentrates are available
  – Rare specific plasma protein deficiencies (eg C1 inhibitor) when recombinant products are unavailable

• Contraindications
  – Volume expansion
  – Coagulation factor deficiencies for which specific therapy exists (eg Vitamin K, cryoprecipitate AHF)
FFP

• Dosage: Volume dependent on clinical situation and patient size
  – 2 units at a time in adults (common practice)
  – 10-20 mL/kg (adults)
  – 10-15 mL/kg (neonates)

• Administration
  – Compatibility tests unnecessary
  – ABO compatible with recipient RBC
  – Thaw at 30-37°C

• Storage: -18°C for 1 year, -65°C for 7 years, or 1-6°C for 24 hours after thawing
A national study of plasma use in critical care: clinical indications, dose and effect on prothrombin time

Simon J Stanworth¹, Timothy S Walsh², Robin J Prescott³, Robert J Lee³, Douglas M Watson⁴, Duncan Wyncoff⁵ and for the Intensive Care Study of Coagulopathy (ISOC) investigators

• Prospective, multicenter, observational study
• 29 adult UK general ICUs over 8 weeks
• 1923 admissions, 12.7% received FFP, 404 treatment episodes
• Aims
  – Determine reasons for administering FFP
  – Determine how bleeding and coagulopathy influence dose
  – Determine the PT/INR triggers used and their relationship to dose
  – Determine changes in PT/INR after FFP administration

### Reasons for FFP Administration

#### Table 1: FFP administered in relation to the three approaches to classifying the circumstances of administration

<table>
<thead>
<tr>
<th>Variable</th>
<th>FFP units (median, first to third quartile)</th>
<th>FFP volume, ml (median, first to third quartile)</th>
<th>FFP dose, ml kg⁻¹ (median, first to third quartile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason given by clinician at time of FFP transfusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coagulopathy with bleeding (n = 185)</td>
<td>3 (2 to 4)</td>
<td>875 (558 to 1104)</td>
<td>11.1 (7.8 to 15.3)</td>
</tr>
<tr>
<td>Coagulopathy without bleeding (n = 138)</td>
<td>2 (2 to 4)</td>
<td>561 (509 to 854)</td>
<td>8.9 (6.8 to 13.1)</td>
</tr>
<tr>
<td>No bleeding prior to procedure (n = 59)</td>
<td>2 (2 to 4)</td>
<td>560 (528 to 1017)</td>
<td>9.8 (6.9 to 13.0)</td>
</tr>
<tr>
<td>𝑃 value for differences across groups</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.009</td>
</tr>
<tr>
<td>All (N = 404)</td>
<td>3 (2 to 4)</td>
<td>736 (536 to 1092)</td>
<td>10.2 (7.0 to 14.1)</td>
</tr>
<tr>
<td>Clinically significant haemorrhage recorded on day of transfusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (n = 215)</td>
<td>2 (2 to 4)</td>
<td>561 (517 to 1017)</td>
<td>9.1 (6.7 to 13.2)</td>
</tr>
<tr>
<td>Yes (n = 189)</td>
<td>3 (2 to 4)</td>
<td>875 (558 to 1100)</td>
<td>11.1 (7.9 to 14.7)</td>
</tr>
<tr>
<td>𝑃 value for differences across groups</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.006</td>
</tr>
<tr>
<td>Use of FFP in relation to occurrence of PT prolongation during ICU admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FFP administered but no PT prolongation occurred at any time during ICU admission (n = 64)</td>
<td>2 (2 to 4)</td>
<td>568 (502 to 936)</td>
<td>8.5 (5.7 to 12.6)</td>
</tr>
<tr>
<td>PT prolongation occurred during ICU admission, but FFP administered out with an episode of PT prolongation (n = 63)</td>
<td>2 (2 to 4)</td>
<td>570 (535 to 1077)</td>
<td>8.6 (6.3 to 13.7)</td>
</tr>
<tr>
<td>FFP administered during an episode of PT prolongation (n = 277)</td>
<td>3 (2 to 4)</td>
<td>806 (542 to 1092)</td>
<td>10.8 (7.3 to 14.4)</td>
</tr>
<tr>
<td>𝑃 value for differences across groups</td>
<td>0.11</td>
<td>0.037</td>
<td>0.014</td>
</tr>
</tbody>
</table>

*FFP, fresh frozen plasma; PT, prothrombin time; ICU, intensive care unit.*
Figure 1 Doses of fresh frozen plasma administered. Graphed histogram results summarising the range of doses of fresh frozen plasma (FFP) given in treatment episodes during intensive care unit (ICU) stay.

Median: 10.8 mL/kg
### Table 3 Median (first to third quartile) FFP dose (ml/kg) administered for different pretransfusion INR values

<table>
<thead>
<tr>
<th>INR value preceding FFP treatment</th>
<th>Median FFP dose per treatment, ml/kg (first to third quartile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1.5</td>
<td>8.9 (5.8 to 13.9)</td>
</tr>
<tr>
<td>1.6 to 2.0</td>
<td>9.7 (6.7 to 15.3)</td>
</tr>
<tr>
<td>2.1 to 2.5</td>
<td>13.8 (8.6 to 18.7)</td>
</tr>
<tr>
<td>2.6 to 3.0</td>
<td>13.7 (7.8 to 24.2)</td>
</tr>
<tr>
<td>&gt;3.0</td>
<td>15.7 (11.4 to 22.1)</td>
</tr>
</tbody>
</table>

*FFP, fresh frozen plasma; INR, international normalised ratio. Results for FFP dose administered by level of pretransfusion INR are shown. P < 0.001 across the groups (Kruskal-Wallis test).*

Effects of FFP on INR

Plasma Frozen Within 24 Hours After Phlebotomy (PF24)

- Separated and frozen at -18°C within 24 hours from collection
- Content: Non-labile plasma proteins (FVIII significantly reduced, FV variable)
- Action: Source of plasma proteins for individuals with deficiency of or defective plasma proteins
- Indications: Similar to FFP
- Contraindications: Similar to FFP; not for treatment of deficiencies of labile coagulation factors

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Plasma Cryoprecipitate Reduced

- Source: FFP after removal of cryoprecipitate
- Refrozen at -18°C within 24 hours
- Action: Source of plasma proteins except for fibrinogen, Factor VIII, Factor XIII and vWF
- Content: Coagulation factors
- Indications
  - Transfusion or plasma exchange in TTP
  - Coagulation factor deficiencies

Circular of Information for the Use of Human Blood and Blood Components.
www.aabb.org
Plasma Cryoprecipitate Reduced

- Contraindications
  - Substitute for FFP, Plasma Frozen Within 24 Hours After Phlebotomy, or Thawed Plasma

- Dosage and administration: Similar to FFP
Thawed Plasma

• Source: FFP or Plasma frozen within 24 hours after phlebotomy
• Action: Source of plasma proteins
• Content: Stable coagulation factors (levels similar to FFP), labile coagulation factors (variably reduced)
• Indications
  – Replacement of multiple plasma coagulation factors
  – Massive transfusion
  – Warfarin reversal

Circular of Information for the Use of Human Blood and Blood Components.
www.aabb.org
Thawed Plasma

• Contraindications
  – DIC
  – Volume expansion
  – Coagulation factor deficiencies for which specific therapy exists (eg Vitamin K, cryoprecipitate AHF)

• Dosage and Administration: Similar to FFP

• Storage: 1-6°C for up to 4 days after the initial 24-hour post-thaw period

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org
Liquid Plasma

• Source: Whole blood
• Separated within 5 days after the expiration date of whole blood
• Action: Source of plasma proteins
• Indications
  – Massive transfusion due to life-threatening trauma/hemorrhages
  – Coagulation deficiencies

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org
Liquid Plasma

- Contraindications
  - Similar to FFP
  - Treatment of isolated coagulation factor deficiencies where other products are available with higher concentrations of the specific factor

- Dosage and administration: Similar to FFP

- Storage: 1-6°C
Octaplas

- S/D treated, pooled human plasma indicated for
  - Replacement of multiple coagulation factors in patients with acquired deficiencies due to liver disease or undergoing cardiac surgery or liver transplant
  - Plasma exchange in patients with TTP

<table>
<thead>
<tr>
<th>Production Step</th>
<th>Virus Reduction Factor [log_{10}]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV-1</td>
</tr>
<tr>
<td>S/D treatment [log_{10}]</td>
<td>≥ 6.18</td>
</tr>
<tr>
<td>Global Reduction Factor</td>
<td>≥ 6.18</td>
</tr>
</tbody>
</table>

HIV-1: Human Immunodeficiency Virus – 1
PRV: Pseudorabies Virus
BVDV: Bovine Viral Diarrhea Virus
SBV: Sindbis Virus
Octaplas

- Studies in patients (n=28) undergoing orthotopic liver transplantation showed an equal correction of clotting factors, PTT, INR and no seroconversion for HIV, HBV, or HCV between SD FFP and FFP (Freeman et al. Vox Sang 1998; 74: Suppl.1:225-229)

- Studies in patients (n=67) undergoing open-heart surgery showed that SD FFP and FFP resulted in a similar rise in coagulation factors and decrease in PT and PTT (Haubelt et al. Vox Sang 2002; 82.1:9-14)
Intercept

- Pathogen inactivation using amotosalen hydrochloride (a synthetic psoralen compound)
  - Reversibly intercalates into the helical regions of DNA and RNA
  - Requires long-wavelength (320 to 400nm) ultraviolet light (UVA) for activation
- FDA approved in 2014

Intercept

Covalent bonds with pyrimidine bases
<table>
<thead>
<tr>
<th>Viruses</th>
<th>Extent of inactivation* (log₁₀ reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enveloped viruses</strong></td>
<td></td>
</tr>
<tr>
<td>HIV-1 (cell-associated)***</td>
<td>&gt;6.1</td>
</tr>
<tr>
<td>HIV-1 (cell-free)</td>
<td>&gt;6.2</td>
</tr>
<tr>
<td>Clinical isolate of HIV-1</td>
<td>&gt;4.4</td>
</tr>
<tr>
<td>Clinical isolate of HIV-2</td>
<td>&gt;7.5</td>
</tr>
<tr>
<td>Latent proviral HIV-1</td>
<td>inactivated to the limit of detection</td>
</tr>
<tr>
<td>HBV (strain MS.2)</td>
<td>&gt;5.5</td>
</tr>
<tr>
<td>HCV (strain Hutchison)</td>
<td>&gt;4.5</td>
</tr>
<tr>
<td>HTLV-I (human T-cell lymphotropic virus)***</td>
<td>4.7**</td>
</tr>
<tr>
<td>HTLV-II (human T-cell lymphotropic virus)***</td>
<td>5.1**</td>
</tr>
<tr>
<td>Cell-associated cytomegalovirus (CMV)***</td>
<td>&gt;5.9</td>
</tr>
<tr>
<td>Bovine viral diarrhea virus (BVDV, model virus for human HCV)</td>
<td>&gt;6.0</td>
</tr>
<tr>
<td>Duck hepatitis B virus (DHBV, model virus for human HBV)</td>
<td>&gt;6.2</td>
</tr>
<tr>
<td>West Nile virus</td>
<td>&gt;6.0</td>
</tr>
<tr>
<td>SARS-CoV (human corona virus)</td>
<td>&gt;5.8</td>
</tr>
<tr>
<td>Chikungunya virus</td>
<td>&gt;6.4</td>
</tr>
<tr>
<td>Influenza A H5N1 virus (avian influenza)</td>
<td>&gt;5.0</td>
</tr>
<tr>
<td><strong>Non-enveloped viruses</strong></td>
<td></td>
</tr>
<tr>
<td>B19tongue virus, type 11</td>
<td>&gt;5.0</td>
</tr>
<tr>
<td>Calcivirus</td>
<td>1.7–2.4</td>
</tr>
<tr>
<td>Human adenovirus-5</td>
<td>&gt;5.0</td>
</tr>
<tr>
<td>Parvo (parovirus B19)</td>
<td>3.5 to &gt;5.0</td>
</tr>
</tbody>
</table>

*"** refers to inactivation below the limit of detection of the assay. In some cases assays have a very small dynamic range due to limits on attainable virus titers.

**Inherent low-level background in non-infected indicator cells precludes > of HTLV.

***Intracellular.

<table>
<thead>
<tr>
<th>Bacterial species</th>
<th>Extent of inactivation* (log₁₀ reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram-negative bacteria</td>
<td></td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>&gt;6.4</td>
</tr>
<tr>
<td><em>Serratia marcescens</em></td>
<td>&gt;6.7</td>
</tr>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
<td>&gt;5.6</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>4.5</td>
</tr>
<tr>
<td><em>Salmonella choleraesuis</em></td>
<td>&gt;6.2</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>&gt;5.9</td>
</tr>
<tr>
<td><em>Enterobacter cloacae</em></td>
<td>5.9</td>
</tr>
<tr>
<td><strong>Gram-positive bacteria</strong></td>
<td></td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td>&gt;6.6</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>6.6</td>
</tr>
<tr>
<td><em>Streptococcus pyogenes</em></td>
<td>&gt;6.8</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>&gt;6.5</td>
</tr>
<tr>
<td><em>Corynebacterium minutissimum</em></td>
<td>&gt;6.3</td>
</tr>
<tr>
<td><em>Bacillus cereus (includes spores)</em></td>
<td>3.6</td>
</tr>
<tr>
<td><em>Bacillus cereus (vegetative)</em></td>
<td>&gt;6.0</td>
</tr>
<tr>
<td><em>Bifidobacterium adolescentis</em></td>
<td>&gt;6.5</td>
</tr>
<tr>
<td><em>Propionibacterium acnes</em></td>
<td>&gt;6.7</td>
</tr>
<tr>
<td><em>Lactobacillus species</em></td>
<td>&gt;6.9</td>
</tr>
<tr>
<td><em>Clostridium perfringens (vegetative form)</em></td>
<td>&gt;7.0</td>
</tr>
<tr>
<td>Spirochete bacteria</td>
<td></td>
</tr>
<tr>
<td><em>Treponema pallidum (syphilis)</em></td>
<td>&gt;6.8 to ≤7.0</td>
</tr>
<tr>
<td><em>Borrelia burgdorferi (Lyme disease)</em></td>
<td>&gt;6.8</td>
</tr>
</tbody>
</table>

*"** refers to inactivation below the limit of detection of the assay.
## Intercept

<table>
<thead>
<tr>
<th>Parasites</th>
<th>Extent of inactivation* (log_{10} reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Plasmodium falciparum</em> <strong>(malaria)</strong></td>
<td>≥6.0</td>
</tr>
<tr>
<td><em>Trypanosoma cruzi</em> <strong>(Chagas’ disease)</strong></td>
<td>&gt;5.3</td>
</tr>
<tr>
<td><em>Leishmania mexicana</em> <strong>(metacyclic promastigote stage)</strong></td>
<td>&gt;5.0</td>
</tr>
<tr>
<td><em>Leishmania major Jish</em> <strong>(amastigote stage)</strong></td>
<td>&gt;4.3</td>
</tr>
<tr>
<td><em>Babesia microti</em> <strong>(babesiosis)</strong></td>
<td>&gt;5.3</td>
</tr>
</tbody>
</table>

*’* refers to inactivation below the limit of detection of the assay.

**Intracellular.
<table>
<thead>
<tr>
<th>Assay system</th>
<th>Evidence of inactivation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In vitro</strong></td>
<td></td>
</tr>
<tr>
<td>Limiting dilution assay</td>
<td>&gt;5.4 log₁₀ reduction of viable T cells</td>
</tr>
<tr>
<td>DNA modification</td>
<td>Approximately one amotosalen adduct per 83 base pairs</td>
</tr>
<tr>
<td>Polymerase chain reaction</td>
<td>Amplification inhibited by amotosalen – DNA adducts</td>
</tr>
<tr>
<td>Cytokine synthesis</td>
<td>Elimination of IL-8, IL-1β synthesis during storage</td>
</tr>
<tr>
<td><strong>In vivo</strong></td>
<td></td>
</tr>
<tr>
<td>Murine transfusion model</td>
<td>Prevention of TA-GVHD in a murine parent to F₁ transfusion model</td>
</tr>
</tbody>
</table>

Intercept

- Coagulation factor retention rates variable but activities within reported reference ranges for conventional plasma
  - Fibrinogen, FVII and FVIII retention: 72-78%
  - FV, FXIII, and VWF:Rco retention: >92%
  - All others retention: >82%

Singh et al. Transfusion. 2006;46:1168-1177
Intercept

- Study comparing effectiveness of plasma (n=207) with Intercept plasma (n=211) in patients undergoing liver transplantation showed
  - No significant difference in volume of plasma transfused
  - More RBCs were transfused in the Intercept plasma group
  - More platelets were transfused in the Intercept plasma group
- Mortality within 7 days of transplantation was not different between the 2 cohorts (8/174, 4.6%) for Intercept plasma versus plasma (6/161, 3.7%, p=0.788) on a per transplant basis or on a per patient basis (8/171, 4.7% Intercept plasma vs plasma 6/157, 3.8%; =0.789)

• Contraindications
  – patients with a history of hypersensitivity reaction to amotosalen or other psoralens
  – neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen

http://intercept-usa.com/warnings-and-contraindications
Cryoprecipitated Antihemophilic Factor (AHF)

- **Source:** FFP thawed at 1-6°C
- **Cold-insoluble precipitate refrozen within 1 hour**
- **Volume:** 5-20 mL
- **Content:** Fibrinogen, FVIII, FXIII, vWF and fibronectin

Circular of Information for the Use of Human Blood and Blood Components.
[www.aabb.org](http://www.aabb.org)

Cryoprecipitated AHF

• Indications
  – Fibrinogen deficiency
  – FXIII deficiency
  – vWD (second line)
  – Hemophilia A (second line)
  – Uremic bleeding (second line)

• Contraindications
  – vWD or FVIII deficiencies if factor concentrates available

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Cryoprecipitated AHF

• Dosage and administration
  – For hypofibrinogenemia, to raise plasma fibrinogen by 50-100 mg/dL
    • Number of bags = 0.2 x body weight in kg
  – For hemophilia A
    • Number of bags = (desired FVIII increment % x 40 x body weight in kg)/average FVIII units per bag
  – For vWD
    • 1 bag per 10 kg body weight
  – 50-60% in vivo recovery
  – Compatibility testing unnecessary (ABO compatible preferred, Rh type irrelevant)

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Cryoprecipitated AHF

- Storage
  - -18°C for 1 year or 20-24°C after thawing
  - Transfuse within 6 hours if single unit or pooled using an FDA-cleared sterile connecting device
  - Transfuse within 4 hours after entering container without using an FDA-cleared sterile connecting device
Quality Control

<table>
<thead>
<tr>
<th>Component</th>
<th>AABB</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryoprecipitated AHF</td>
<td>Minimum of 150 mg of fibrinogen and a minimum of 80 IU of coagulation Factor VIII. In tests on pooled components, the pool shall contain a minimum of 150 mg fibrinogen and 80 IU of coagulation Factor VIII times the number of components in the pool.</td>
<td>Test 4 representative units each month for Factor VIII (≥80 IU/unit).</td>
</tr>
</tbody>
</table>
Platelets

- Source: Whole blood or apheresis collection
- Volume: 40-60 mL (whole blood derived) or 200-250 mL (apheresis derived)

Circular of Information for the Use of Human Blood and Blood Components.

[www.aabb.org](http://www.aabb.org)
Platelets

• Action: Normal hemostasis
• Content: ≥5.5 x 10^{10} platelets in 40 mL to 70 mL plasma (whole blood derived) or ≥3 x 10^{11} platelets (apheresis derived); leukocytes
• Indications
  – Thrombocytopenia
  – Thrombocytopathy
  – Active platelet-related bleeding
  – Risk of bleeding

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Platelets

• Contraindications
  – Bleeding unrelated to thrombocytopenia or thrombocytopathy
  – Platelet count >100,000/µl without thrombocytopathy
  – Thrombocytopathy extrinsic to platelets (eg uremia, vWD, hyperglobulinemia)
  – Activation or autoimmune destruction of endogenous platelets (eg HIT, TTP, ITP) unless life threatening hemorrhage
Platelets

• Dosage and Administration
  – Compatibility testing unnecessary
  – Donor plasma should be ABO compatible with recipient RBCs for infants or massive transfusion
  – Dosage dependent on clinical situation
    • Therapy: 1 dose of apheresis platelets or 4 to 6 units of whole blood-derived platelets
    • Prophylaxis: similar to therapeutic dose and repeated in 1 to 3 days (3-4 day lifespan in vivo)

Circular of Information for the Use of Human Blood and Blood Components. www.aabb.org
Platelets

• Expected effects
  – 1 unit of whole blood derived platelets for 70 kg adult: 5,000 to 10,000/µl
  – 1 unit of whole blood derived platelets for 18 kg child: 20,000/µl
  – Corrected count increment (CCI) = (platelet count increment in per µl) x BSA in m² / platelets transfused x 10¹¹

• Storage: 20-24°C with gentle agitation for 5 days
7 Day Platelets

- FDA draft guidance on “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion” (March 2016)
- Secondary testing of platelets for the purpose of extending the dating period of platelet components past 5 days must be conducted only with a test labeled as a “safety measure” according to its instructions for use
- Platelets must be stored in FDA-cleared or approved 7-day platelet storage containers

7 Day Platelets

• Secondary testing modalities
  • FDA-cleared rapid bacterial detection device labeled as a “safety measure” within 24 hours prior to transfusion for day 6 or day 7 platelets; or
  • Culture-based bacterial detection device labeled as a “safety measure” on day 4 with a 48-hour extension through day 6 if negative result at least 24 hours after sampling; or
  • Culture-based bacterial detection device labeled as a “safety measure” on day 5 with a 48-hour extension through day 7 if negative result at least 24 hours after sampling

Intercept Platelets

• May be stored for 5 or 7 days according to institutional blood banking procedures
• Safety profile of amotosalen treated platelets similar to that previously reported for conventional platelets
• Recovery and survival of treated platelets in healthy individuals showed a statistically significant in-vivo lower recovery (42.5 vs 50.3%) and survival (4.8 vs 6 days)
Intercept Platelets

- Meta-analysis of bleeding complications showed
  - Higher risk of clinically significant bleeding complications in association with treatment with the Intercept system when all studies included

**Intercept Platelets**

- Substitution of the results from the initial report of the SPRINT randomized controlled trial for the results from the expanded safety analysis of that study.
  - Initial report of SPRINT RCT did not present results on all bleeding complications.
- For all three comparisons, the 95%CI of the OR includes the null value of 1, and the difference between the arms is not statistically significant (P>0.05).

---

# Quality Control

<table>
<thead>
<tr>
<th>Component</th>
<th>AABB</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets</td>
<td>Demonstrate that at least 90% of units sampled contain ( \geq 5.5 \times 10^{10} ) platelets and have a pH ( &gt; 6.2 ) at the end of allowable storage</td>
<td>Test 4 units each month at the end of storage interval for pH ( \geq 6.2 ). Also, centrifugation conditions must ensure platelet count of ( \geq 5.5 \times 10^{10} )/unit in 75% of the units.</td>
</tr>
<tr>
<td>Apheresis platelets</td>
<td>Demonstrate that at least 90% of units sampled contain ( \geq 3.0 \times 10^{11} ) platelets and that at least 90% of units have a pH ( \geq 6.2 ) at the end of allowable storage. At a minimum, 95% of units sampled shall contain a residual leukocyte count (&lt; 5 \times 10^6 ) for leukocyte-reduced units.</td>
<td>Number of units to test must be sufficient to allow 95% confidence that 75% of component’s platelet yield is ( \geq 3.0 \times 10^{11} )/unit. Similarly, test sufficient number for pH ( \geq 6.2 ) and residual WBCs (&lt; 5.0 \times 10^6 )/unit (for leukocyte-reduced units) to achieve 95% confidence that 95% of components will meet the requirements.</td>
</tr>
</tbody>
</table>
Granulocytes

- Source: Apheresis collection after stimulation with G-CSF ± corticosteroids
- Volume: 250-300 mL
- Hematocrit: ~10%

www.bing.com/images/search?q=granulocytes
Granulocytes

- **Action:** Kills bacteria and fungi
- **Content:** leukocytes (>1 x 10^{10} granulocytes), platelets, RBCs (20 mL to 50 mL)
- **Indications**
  - Infections with gram negative bacteria and fungi unresponsive to antimicrobial therapy in the setting of neutropenia (ANC < 500/µl) with expected marrow recovery
  - Neonatal sepsis
  - Hereditary neutrophil function defects (eg CGD)

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Granulocytes

• Contraindications
  – Prophylactic use in non-infected patients

• Dosage and administration
  – Transfuse ASAP
  – Do not use leukocyte reduction filters
  – ABO compatible
  – Irradiated
  – Continue daily until infection cured, defervescence occurs, ANC > 500/µl

• Storage: 20 to 24°C without agitation for no more than 24 hours
# Quality Control

<table>
<thead>
<tr>
<th>Component</th>
<th>AABB</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apheresis Granulocytes</td>
<td>Unless prepared for neonates, each granulocyte unit must have a minimum of $1.0 \times 10^{10}$ granulocytes in at least 75% of the units tested.</td>
<td>None</td>
</tr>
</tbody>
</table>

Plasma Derivatives
• **Source**: Cold ethanol fractionation (Cohn fractionation) of whole blood or apheresis plasma
• 50-60% of total plasma proteins
• 80-85% of osmotic pressure of plasma

Albumin

• Function
  – Maintains and regulates plasma volume
  – Carrier for physiologic molecules and administered drugs

• Indications
  – Therapeutic plasma exchange
  – Cirrhosis with SBP
  – Large volume therapeutic paracentesis
  – Nephrotic syndrome (second line therapy)
  – Hypoalbuminemia (controversial)
Albumin

• Contraindications
  – Disease states that would be exacerbated by volume expansion (e.g., severe anemia, congestive heart failure, and pulmonary edema)
  – History of anaphylactic reactions

• Dosage and expected effect
  – 5% solution: Expands volume equal to volume infused
  – 25% solution: Expands volume 3.5 times the volume infused
  – Adult: 25 g initially, repeated in 15-30 minutes; maximum 250 g in 48 hour period
  – Pediatric: varies with clinical indication and age
Albumin

• Manufacturing
  – Human plasma
  – 96% protein composition
  – Contaminants: non-albumin proteins, endotoxins, trace metals, prekalikrein activator, bradykinin, sodium, potassium and stabilizers
  – Viral inactivation: Heat treatment (60°C for 10 hours) and cold ethanol fractionation

• Storage
  – Room temperature
  – 2 years
Albumin

• Adverse reactions
  – Changes in vital signs
  – Nausea
  – Fever/chills
  – Allergic reaction
  – Hypocalcemia
  – Aluminum toxicity
  – Circulatory overload
Intravenous Immune Globulin (IVIG)

• Source: Cold ethanol fractionation (Cohn fractionation) of whole blood or apheresis plasma
• Content: Mostly IgG
  – Concentrated, purified and sterilized

www.bing.com/images/search?q=intravenous+immune+globulin
## IVIG Indications

<table>
<thead>
<tr>
<th>FDA-approved</th>
<th>Off-label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary immune deficiency</td>
<td>Aplastic anemia secondary to parvovirus</td>
</tr>
<tr>
<td>Secondary immune deficiency</td>
<td>CIDP</td>
</tr>
<tr>
<td>ITP</td>
<td>Dermatomyositis</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>Guillan-Barre syndrome</td>
</tr>
<tr>
<td>HDFN</td>
<td>Hypogammaglobulinemia associated with multiple myeloma</td>
</tr>
<tr>
<td>IgM paraproteinemic demyelinating neuropathy</td>
<td></td>
</tr>
<tr>
<td>Lambert-Eaton myasthenic syndrome</td>
<td></td>
</tr>
<tr>
<td>Multifocal motor neuropathy</td>
<td></td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td></td>
</tr>
<tr>
<td>Myasthenia gravis</td>
<td></td>
</tr>
<tr>
<td>NAIT</td>
<td></td>
</tr>
<tr>
<td>Organ transplantation</td>
<td></td>
</tr>
<tr>
<td>PTP</td>
<td></td>
</tr>
<tr>
<td>Sepsis and septic shock in adults</td>
<td></td>
</tr>
<tr>
<td>Stiff-person syndrome</td>
<td></td>
</tr>
</tbody>
</table>

IVIG

• Half life: 21-28 days
• Mechanism of action
  – Congenital Ig deficiency (hypo or agammaglobulinemia): supplements or replaces missing antigen-specific humoral component
  – Autoimmune disorders: immunomodulation
IVIG

• Mechanism of immunomodulation
  – Macrophage Fc receptor blockage by immune complexes formed between IVIG and native antibodies
  – Modulation of complement
  – Suppression of antibody production
  – Suppression of inflammatory cytokines and chemokines
  – Anti-idiotypic regulation of autoreactive B lymphocytes or antibodies
IVIG

• Adverse reactions
  – 2-10% of infusions
  – Result of allergy or rate/dose of infusion
  – Differ among different preparations
  – Erythema, phlebitis, eczema, fever, chills, myalgias, malaise, flushing, rash, diaphoresis, pruritus, bronchospasm, chest pain, back pain, dizziness, blood pressure changes, nausea, vomiting, headache
  – Anaphylactic reaction (IgA deficient recipients), aseptic meningitis, renal failure, thromboembolic events, passively acquired antibodies, hemolytic transfusion reactions, TRALI (1 case)
Rh Immune Globulin (RhIg)

- **Source:** Cold ethanol fractionation (Cohn fractionation) of plasma
- **Content:** IgG antibodies against D antigen

RhIg

• Indications
  – Prevent immunization to D antigen in D-negative individuals
    • Perinatal administration (decreases risk from 13% to 0.1%)
    • D-positive blood product transfusion to D-negative individual
  – ITP

• Mechanism of action: unknown

• Route of administration: IM or IV
RhIg Dosage

- **Perinatal Administration**

<table>
<thead>
<tr>
<th>Vial size</th>
<th>IU</th>
<th>Whole blood (mL)</th>
<th>RBCs (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50µg</td>
<td>250</td>
<td>5</td>
<td>2.5</td>
</tr>
<tr>
<td>120µg</td>
<td>600</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>300µg</td>
<td>1500</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>1000µg</td>
<td>5000</td>
<td>100</td>
<td>50</td>
</tr>
</tbody>
</table>

- **ITP**
  - Hgb ≥ 10 g/dL : 50 µg/kg
  - Hgb 8-10 g/dL : 25-40 µg/kg
  - Hgb < 8 g/dL: ?

- **Half-life: 21 days**
RhIg

• Adverse reactions
  – Low dose: Fever, chills, pain at injection site, hypersensitivity reactions
  – High dose: mild hemolytic reaction and intravascular hemolysis
    • Hemoglobinuria, pallor, hypotension, sinus tachycardia, oliguria, anuria, edema, dyspnea, ecchymosis, prolonged bleeding time, death
  – TRALI
vWF Concentrate

• **Source:** Human plasma

# vWF Concentrate

<table>
<thead>
<tr>
<th>Product</th>
<th>FDA approval</th>
<th>vWF:FVIII</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alphanate</td>
<td>Yes (surgery, type 1 and 2 NOT responsive to DDAVP)</td>
<td>1:1 HMWM not well retained</td>
</tr>
<tr>
<td>Humate P</td>
<td>Yes (all types vWD)</td>
<td>2:1 HMWM well retained</td>
</tr>
<tr>
<td>Koate-DVI</td>
<td>No</td>
<td>&lt;1:1 HMWM not well retained</td>
</tr>
</tbody>
</table>
vWF Concentrate

• Indication: vWD

• Dosage and expected effect
  – 1 unit of vWF:Rco will raise vWF activity by 2%

• Half-life: 10-12 hours

• Adverse reactions
  – Infection
  – Thrombosis (with high levels of FVIII)
Factor VIII Concentrate

- **Source:** Human plasma or recombinant

Factor VIII Concentrate

- **Indications**
  - Hemophilia A
  - Acquired factor VIII deficiency

- **Dosage and expected effect**
  - 1 unit/kg will raise plasma level by 2%

- **Half-life**: 12 hours

- **Adverse reactions**
  - Inhibitor development
  - Infection
  - Allergic reaction
## Factor VIII Concentrate

<table>
<thead>
<tr>
<th>Product</th>
<th>vWF content</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemofil M</td>
<td>Low</td>
<td>Human plasma</td>
</tr>
<tr>
<td>Monoclate-P</td>
<td>Low</td>
<td>Human plasma</td>
</tr>
<tr>
<td>Alphanate</td>
<td>High</td>
<td>Human plasma</td>
</tr>
<tr>
<td>Koate DVI</td>
<td>High</td>
<td>Human plasma</td>
</tr>
<tr>
<td>Humate-P</td>
<td>High</td>
<td>Human plasma</td>
</tr>
<tr>
<td>Recombinant</td>
<td>None</td>
<td>Recombinant-1(^{st}) generation</td>
</tr>
<tr>
<td>Helixate FS</td>
<td>None</td>
<td>Recombinant-2(^{nd}) generation</td>
</tr>
<tr>
<td>Kogenate FS</td>
<td>None</td>
<td>Recombinant-3(^{rd}) generation</td>
</tr>
<tr>
<td>Advate</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Xyntha</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Factor IX Concentrate

- **Source**: human plasma or recombinant
  - Plasma-derived: AlphaNine SD, Mononine
  - Recombinant: BeneFIX
Factor IX Concentrate

• Indication: hemophilia B
• Dosage and expected effect
  – 1 U/kg infused raises plasma level by 1%
  – 1.4 U/kg for young children; 1.2 U/kg for adults (recombinant)
• Half-life: 24 hours
• Adverse reactions
  – Inhibitor development
  – Infection
  – Allergic reaction
Prothrombin Complex Concentrate (PCC)

- **Source:** Pooled human plasma
- **Content:** Factor II, (VII), IX X; Protein C and S (variable amounts)
PCC

• Products
  – 3-factor PCC: Bebulin VH, Profilnine SD
  – 4-factor PCC: Kcentra
  – Activated PCC(aPCC): FEIBA VH

• Indications
  – Congenital prothrombin or Factor X deficiency
  – Warfarin reversal
  – Hemophilia A or B with inhibitors
  – Acquired factor VIII inhibitors

• Contraindications
  – Hemophilia B
PCC

• Dosage (Labeled by Factor IX IUs)
  – Warfarin reversal: 500 IU (INR<5) or 25-50 IU/kg (INR>5)
  – Factor VIII or IX inhibitors: 50-100 IU/kg every 8-12 hours (max 200 IU/kg)

• Adverse reactions
  – Thrombosis
  – DIC
  – Allergic reaction
  – Infection
  – HIT (Bebulin VH)
Factor VII Concentrate

- **Source**: Recombinant (human FVII gene expressed in baby hamster kidney cells)
- **Product**: Novoseven

Factor VII Concentrate

• Indications
  – Congenital hemophilia with inhibitor
  – Acquired FVIII inhibitor
  – FVII deficiency
  – Trauma (off label)
  – Surgery (off label)
  – Warfarin reversal (off label)

• Pathophysiology
  – Dose to physiologic level: Binds to tissue factor
  – Dose to superphysiologic level: Binds to tissue factor and activated platelets; activates FX
Factor VII Concentrate

• Dosage
  – Congenital hemophilia with inhibitor: 90-120 µg/kg
  – Acquired factor VIII inhibitor: 70-90 µg/kg
  – Congenital factor VII deficiency: 15-30 µg/kg

• Adverse reactions
  – Allergic reaction
  – Arterial and venous thrombosis
Thank you!

Email questions to:
yct2103@cumc.columbia.edu