FRENCH EXPERIENCE IN THE CLINICAL USE OF LYOPHILIZED PLASMA
OVERVIEW

- Presentation of the CTSA
- French military transfusion guidelines
- Blood supply overseas operations
- French lyophilized plasma
  - Production
  - Characteristics
  - In vitro properties
  - FLYP used in French intensive care unit in KAIA
  - Perspectives
SOME ELEMENTS OF HISTORY SINCE 1939

- **WWII**: Jean Julliard used FDP produced in the US
- **1949**: 1st production of French FDP in CTSA
- **1950-1987**: CTSA: 1st European centre for FDP
- **1987-1991**: FDP production stopped: Too many risks of HIV with pooled products
- **1994**: New production of FDP, secured by quarantine & authorized by Blood National authorities
- **2003**: FDP leucoreduced
- **2010**: FDP secured with Amotosalen: 
  - PLYO in French
  - FLYP in English
MISSIONS OF THE CTSA

1. To provide the transfusion support of overseas operations and military hospitals:
   → Produce the «best blood products »
   → Deliver transfusion advice 24 hours a day
   → Ensure hemovigilance and traceability

2. Immuno-haematology center

3. To train military personnel in transfusions for overseas operations

4. Center of cell and tissue therapy

5. Research center specializing on blood and skin
2012: Hemorrhagic shock is the 1st reason of death in combat and the 1st reason of death that is avoidable.

- Coagulopathy occurs early and increases the mortality rate.
EMERGENCY TREATMENT OF WOUNDED BLEEDING IN OVERSEAS OPERATIONS

- Tourniquet
- Haemostatic plasters
- TXA in the first 3 H
- 1 FLYP / 1 RBC
- 5th RBC = Fresh whole blood
  + Bicarbonate
  + Warming
  + Calcium supply
  ± Fibrinogen
  ± Rational use of aFVII
- Hemostatic surgery
OVERVIEW OF UNITS DEPLOYED FOR OVERSEAS OPERATIONS
BLOOD CHAIN TO SUPPLY OVERSEAS OPERATIONS

ROLE 1
POSTE DE SECOURS PRINCIPAL
POSTE DE SECOURS MOBILE

ROLE 2
SECTION CHIRURGICALE MODULAIRE
EXTREMES URGENCES
URGENCES ABSOLUES
URGENCES RELATIVES

ROLE 3
BOPITAL MOBILE DE CAMPAGNE
BOPITAL DES ARMES

ROLE 4

MEDICALISATION DE L'AVANT
REANIMATION CHIRURGICALISATION DE L'AVANT
TRAITEMENT DES URGENCES ABSOLUES DEFINITIF
TRAITEMENT DES URGENCES SECUNDAIRES ET TERTIARES

FWB FLYP
FWB FLYP
RBC FLYP PLAT
CTSA

RBC + FDP + KIT FWB +/- PLAT

onsdag 5. september 2012
BLOOD SUPPLY OVERSEAS OPERATIONS

Red Blood Cells

Lyophilised Plasma

Roles 1

Roles 2 & 3

RDCR Conference 19-21 June 2012
BLOOD SUPPLY OVERSEAS OPERATIONS

RDCR Conference 19-21 June 2012

Onsdag 5. September 2012
FRENCH LYOPHILISED PLASMA IS COLLECTED WITH APERHESIS

Donors are all volunteers and a rigorous selection is applied

RDCR Conference 19-21 june 2012
BIOLOGICAL TESTS PERFORMED

- All blood products:
  - Hemoglobin
  - ABO Rh Kell
  - HIV ½ antibodies & PCR
  - HCV antibodies & PCR
  - HBV antigen & PCR
  - HTLV antibodies
  - Syphilis antibodies
- Some blood products:
  - Chagas antibodies
  - Malaria antibodies
- Only plasma:
  - HLA antibodies
  - Hemostasis tests
  - Residual Amotosalen
FDP SAFETY ISSUE

- Until 2010 FDP was secured by quarantine:
  - It prevents only known infectious risks
  - It imposes deadlines too long to meet the increased demand

- Since 2010 FDP is secured with amotosalen and VU:
  - It’s better to increase supply when needed
  - It meets the recommendations of the French health authorities (AFSSAPS)
  - It prevents both known and unknown infection risks (parasits, viruses, bacteriaes, fungies)
  - It eliminates the residual leukocytes
PROCESS WITH AMOTOSALEN & VU EXPOSITION

Cerus Illuminator
DEEP FREEZING PROCESS

- 25°C
LYOPHILIZATION/CRYODESSICATION PROCESS
Some FFP-IA are selected & mixed:
- Less than 10 different donors (mini-pools)
- Plasma within hemolysins
- Plasma with factor VIII $\geq$ 96%
- Plasma without HLA antibodies

The mixed plasma is distributed aseptically into glass bottles, according European good manufacturing practices:
- Clean rooms
- Air treatment monitoring
- Sterile water
SPECIFIC TESTS TO VALIDATE FLYP

« Liberating » tests: Analysis on a sample bottle

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hémolysines</td>
<td>Nothing</td>
</tr>
<tr>
<td>Titre anti-A</td>
<td>&lt; 1/64</td>
</tr>
<tr>
<td>Titre anti-B</td>
<td>&lt; 1/64</td>
</tr>
<tr>
<td>Agglutinines irrégulières</td>
<td>nothing</td>
</tr>
<tr>
<td>Hemostasis factor VIII</td>
<td>≥ 0,5 UI/mL</td>
</tr>
<tr>
<td>Amotosalen residual</td>
<td>&lt; 2 µM</td>
</tr>
<tr>
<td>Protéines totales</td>
<td>≥ 50 g/L</td>
</tr>
<tr>
<td>Humidité</td>
<td>&lt; 2%</td>
</tr>
<tr>
<td>Temps de reconstitution</td>
<td>&lt; 180 sec</td>
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# IN VITRO PROPERTIES

**Average of 30 plasmas**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Units</th>
<th>PFC-SD</th>
<th>PFC-IA</th>
<th>PFC-Se</th>
<th>FLYP</th>
<th>Physiological norms</th>
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<tbody>
<tr>
<td>Fibrinogen</td>
<td>g/L</td>
<td>2,8</td>
<td>2,7</td>
<td>2,8</td>
<td>2,4</td>
<td>2 - 4</td>
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<tr>
<td>Facteur V</td>
<td>UI/mL</td>
<td>0,9</td>
<td>1,0</td>
<td>1,0 à 1,1</td>
<td>0,7</td>
<td>0,7 – 1,2</td>
</tr>
<tr>
<td>Facteur VIII</td>
<td>UI/mL</td>
<td>0,7</td>
<td>0,8</td>
<td>0,9 à 1,1</td>
<td>0,7</td>
<td>0,5 – 1,5</td>
</tr>
<tr>
<td>Facteur XI</td>
<td>UI/mL</td>
<td>0,8</td>
<td>0,6</td>
<td>0,9 à 1,0</td>
<td>0,7</td>
<td>0,5 – 1,4</td>
</tr>
<tr>
<td>Protéine C</td>
<td>UI/mL</td>
<td>1,0</td>
<td>0,9</td>
<td>1,1 à 1,2</td>
<td>0,9</td>
<td>0,7 – 1,2</td>
</tr>
<tr>
<td>Protéine S</td>
<td>UI/mL</td>
<td>0,6</td>
<td>1,0</td>
<td>1,3 à 1,4</td>
<td>0,9</td>
<td>0,7 – 1,4</td>
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<tr>
<td>Antithrombine III</td>
<td>UI/mL</td>
<td>0,9</td>
<td>1,0</td>
<td>1,0</td>
<td>1,0</td>
<td>0,8 – 1,2</td>
</tr>
<tr>
<td>α2 antiplasmin</td>
<td>UI/mL</td>
<td>0,2</td>
<td>0,8</td>
<td>1,0</td>
<td>0,9</td>
<td>0,8 – 1,2</td>
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12 different FLYP were studied

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<th>Batch 10100267351: stability studies after reconstitution</th>
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<tbody>
<tr>
<td>Room temperature: average of 6 FLYP</td>
</tr>
<tr>
<td>T 0</td>
</tr>
<tr>
<td>TP (%)</td>
</tr>
<tr>
<td>TCK (sec)</td>
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<tr>
<td>Fibrinogen (g/l)</td>
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<tr>
<td>F VIII (UI/ml)</td>
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<tr>
<td>F V (%)</td>
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DILUTION MODEL TRANSFUSION IN INTENSIVE CARE
DILUTION MODEL TRANSFUSION IN INTENSIVE CARE

Blood Sample 40%
DILUTION MODEL TRANSFUSION IN INTENSIVE CARE

Blood Sample 40%

RL 30%

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DILUTION MODEL TRANSFUSION IN INTENSIVE CARE

Blood Sample 40%

RL 30%

FFP 30% FDP RL

onsdag 5. september 2012
DILUTION MODEL TRANSFUSION IN INTENSIVE CARE

Blood Sample 40%

RL 30%

FFP 30%  FDP  RL
IN VITRO DILUTIONS DEMONSTRATE THE EFFICIENCY OF FLYP

TEG

R in minutes

Alpha angle in degrees

Maximal amplitude in mm
IN VITRO DILUTIONS DEMONSTRATE THE EFFICIENCY OF FLYP

TEG

R in minutes

Alpha angle in degrees

Maximal amplitude in mm
MAIN SPECIFICITIES OF THE FRENCH LYOPHILIZED PLASMA

• Universal blood group compatibility.

• 2 years shelf life with room temperature storage.

• Reconstitution time < 6 min.

• Inactivated by amotosalen® process.

• Haemostastic properties controled on each production.
1 bottle with FLYP
1 bottle with water for injection
1 transfusor with vent air intake
1 transfer kit
STUDY ABOUT FLYP USED IN FRENCH INTENSIVE CARE UNIT AT KAIA

- The aim of the study was to assess:
  - The clinical use of FDP in war settings
  - Effect on prothrombin time

- At Kaboul Afghanistan International Airport (KAIA):
  - Role 3 hospital
  - Military structure
  - International team
  - French Intensive Care Unit with 4 physicians

- Global transfusion activity in 2010:
  - 517 RBC
  - 378 FLYP: No FFP available
  - 125 FWB
FLYP USED AT KAIA
February 2010 - February 2011

- Prospective study
- Based on a form filled by physicians after each FLYP transfusion
- Reviewed by a person
- Local Ethic Committee approved the study
Shock was defined at admission based on physician findings:
- Consciousness perturbation
- Pallor
- Delayed capillary refill
- Tachycardia >120 bpm
- Systolic blood pressure <80 mmHg

Mechanism of injury:
- Gunshots wounds 43%
- Polytrauma 25%
- Explosion 11%

67% considered in shock on admission

Outcome after 24 hours: 10% died
**FLYP USED AT KAIA**  
February 2010 - February 2011

Blood products, fluids and agents given prior the use of FDP

<table>
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<tr>
<th></th>
<th>Median</th>
<th>Range</th>
<th>% of patients</th>
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<tbody>
<tr>
<td>Red blood cells (units)</td>
<td>3</td>
<td>1-13</td>
<td>32</td>
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<tr>
<td>Whole blood (units)</td>
<td>4</td>
<td>1-7</td>
<td>5</td>
</tr>
<tr>
<td>Crystalloid (L)</td>
<td>1</td>
<td>0.2-5</td>
<td>56</td>
</tr>
<tr>
<td>Colloid (mL)</td>
<td>500</td>
<td>100-8000</td>
<td>15</td>
</tr>
<tr>
<td>Fibrinogen (g)</td>
<td>1.5</td>
<td>1-3</td>
<td>6</td>
</tr>
</tbody>
</table>
FLYP USED AT KAIA
February 2010 – February 2011

RBC to FDP ratio: 95% = 0.8-1.1
FLYP USED AT KAIA
February 2010 – February 2011

Hemoglobin, Platelets and Fibrinogen levels

Hemoglobin, platelets and fibrinogen levels

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FLYP USED AT KAIA
February 2010 - February 2011

Prothrombin time before and after FDP
FLYP USED AT KAIA

Conclusions

- Relevance of the FLYP to control the coagulopathy of war injuries
- Safety of FLYP
- Ratio RBC: FLYP is conform with the French army resuscitation guidelines
- Recommendation: Use FLYP as early as possible to prevent coagulopathy
Conclusions

Use of Freeze-Dried Plasma in French Intensive Care Unit in Afghanistan

Christophe Martinaud, MD, Sylvain Ausset, MD, Anne Virginie Deshayes, PharmD, Amandine Cauet, Nicolas Demazeau, MD, and Anne Sailliol, MD

Background: Modern warfare causes severe injuries, and despite rapid transportation to theater regional trauma centers, casualties frequently arrive coagulopathic and in shock. Massive hemorrhage management includes transfusion of red blood cells and plasma in a 1:1 ratio. Fresh frozen plasma requires thawing and badly fits the emergency criteria. Since 1994, the French Military Blood Bank has been producing freeze-dried plasma (FDP) and providing it for overseas operation. The aim of our study was to evaluate the use of FDP in war settings and to assess its clinical efficiency and safety. Patients: We performed a prospective study of the FDP delivered at the International Security Assistance Force Role 3 Military Medical Treatment Facility in the Kabul Afghanistan International Airport between February 2010 and February 2011. We included every patient who received at least one unit of FDP. Basic clinical data were recorded at admission. Transfusion requirements were monitored. Biological testing were performed before and after administration of FDP including hemoglobin concentration, platelets count, fibrinogen level, prothrombin time (PT), and thromboelastography.

FLYP USED AT KAIA
Conclusions

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The Journal of TRAUMA® Injury, Infection, and Critical Care • Volume 71, Number 6, December 2011 1761
FLYP USED AT KAIA

Anesthesiology
In Vitro Hemostatic Properties of Freeze-dried Plasma
—Manuscript Draft—

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PERSPECTIVES

• We develop a new tracability sheet easier to use and to report the data

• We develop a new specific application to trace and evaluate the transfusion practices in overseas operations

• We recommend to use earliest the FLYP to prevent coagulopathy:
  – In role 1 and all MEDEVAC
  – In civilian medical units.
CLINICAL and LABORATORY TRACKING FORM
Freeze-dried Plasma (FDP)

1 Form per Transfusion Episode (T.E.)
Return to CTSA*
- Number of FDP units transfused during T.E.: .......... (attach traceability stickers from each unit of FDP used below or on reverse as needed)

- Location of use: .................................. date (D0) and time / 20 .. - H ...
- Patient name (last, first): ........................................ / 
- Date of birth: ...... / ...... / ......

Choose all that apply
- Indication: □ Active hemorrhage □ Hemorrhagic shock (use of vasopressors)
  □ At risk for massive transfusion □ At risk of hemorrhage
- Context: □ Severe blunt trauma □ Gunshot wound/explosive □ Obstetrics
  □ Severe penetrating trauma □ Other (describe): ..................................

Date and time of event/injury: ...... / ...... / 20 .. - H ...

- Concomitant transfusion (describe) □ Whole blood (No.): .... □ Platelets (No.): .... □ PRBCs (No.): ....
□ IV Fluids (type/ml): .......................................................... □ 1 g Tranexamic acid
□ Other blood-derived products (type/vol): ...................................

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<th>AFTER T.E.</th>
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<tbody>
<tr>
<td>PT INR</td>
<td>Date if ≠ D0</td>
<td>Date if ≠ D0</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>Time</td>
</tr>
<tr>
<td>Fibrinogen g/L</td>
<td>g/L</td>
<td>g/L</td>
</tr>
</tbody>
</table>

CLINICAL EVOLUTION AFTER TRANSFUSION OF FDP:

- Clinical tolerance: □ Good □ Adverse event (time from infusion of FDP):
□ Type of AE: ...................................
- Effect on Bleeding: □ Stop □ Decrease □ Stabilization □ No effect
- Clinical evolution: □ Favorable □ Stabilization □ Worsening □ Death
- Transfer of patient? □ NO □ YES (treatment facility): ..................................

Name and signature of Physician responsible for transfusion: ..................................
CLINICAL and LABORATORY TRACKING FORM
Freeze-dried Plasma (FDP)

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* C.T.S.A. 1 rue du Lt Raoul Bensy – 92141 CLAMART Cedex. Tel.: 01 41 46 72 22 – Fax: 01 41 46 72 74
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Choose all that apply

- Indication: □ Active hemorrhage □ Hemorrhagic shock (use of vasopressor) □ At risk for massive transfusion □ At risk of hemorrhage

- Context: □ Severe blunt trauma □ Gunshot wound/explosive □ Obstetrics □ Severe penetrating trauma □ Other (describe):

Date and time of event/injury: / ...... / 20......- ......H ........

- Concomitant transfusion (describe): □ Whole blood (No.): ...... □ Platelets (No.): ...... □ PRBCs (No.): ......
- IV Fluids (type/mL): ........................................ □ 1 g Tranexamic acid.
- Other blood-derived products (type/amount): ........................................

<table>
<thead>
<tr>
<th>COAGULATION TESTING</th>
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CLINICAL EVOLUTION AFTER TRANSFUSION OF FDP:

- Clinical tolerance: □ Good □ Adverse event (time from infusion of FDP): ........................................
- Effect on Bleeding: □ Stop □ Decrease □ Stabilization □ No effect
- Clinical evolution: □ Favorable □ Stabilization □ Worsening □ Death
- Transfer of patient*: □ NO □ YES (treatment facility): ........................................

Name and signature of Physician responsible for transfusion: ........................................

* C.T.S.A. 1 rue du Lt Raoul Bessy – 92140 CLAMART Cedex; Tel.: 01.41.46.72.23 – Fax: 01.41.46.72.74

onsdag 5. september 2012
CLINICAL and LABORATORY TRACKING FORM  
Freeze-dried Plasma (FDP)

1 Form per Transfusion Episode (T.E.)  
Return to CTSA*

- Number of FDP units transfused during T.E.: ............ (attach traceability stickers from each unit of FDP used below or on reverse as needed)

- Location of use: ........................................ date (D0) and time... / ... / 20... - ... H ....
- Patient name (last, first): ................................ / ................................
- Date of birth: ...... / ...... / ......

Choose all that apply

- Indication: □ Active hemorrhage □ Hemorrhagic shock (use of vasopressors)
□ At risk for massive transfusion □ At risk of hemorrhage

- Context: □ Severe blunt trauma □ Gunshot wound/explosive □ Obstetrics
□ Severe penetrating trauma □ Other (describe):

Date and time of event/injury: / / 20... - ... H

- Concomitant transfusion (describe) □ Whole blood (No): .... □ Platelets (No): .... □ PRBCs (No): ....
□ IV Fluids (type/ml): .............................................. □ 1 g Tranexamic acid.
□ Other blood-derived products (type/amount):

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CLINICAL EVOLUTION AFTER TRANSFUSION OF FDP:

- Clinical tolerance: □ Good □ Adverse event (time from infusion of FDP): ................................ Type of AE:
- Effect on Bleeding: □ Stop □ Decrease □ Stabilization □ No effect
- Clinical evolution: □ Favorable □ Stabilization □ Worsening □ Death
- Transfer of patient* □ NO □ YES (treatment facility): ............

Name and signature of Physician responsible for transfusion: ........................................

* Version 11.20.11  
* C.T.S.A. 1 rue du Lt Raoul Betanc – 92141 CLAMART Cedex, Tel: 01.41.46.72.22 – Fax: 01.41.46.72.74
CLINICAL and LABORATORY TRACKING FORM
Freeze-dried Plasma (FDP)

1 Form per Transfusion Episode (T.E.)
Return to CTSA*

- Number of FDP units transfused during T.E.: ......... (attach traceability stickers from each unit of FDP used below or on reverse as needed)

- Location of use: .................................. date (D0) and time..... / ...... / 20..... - H ....
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Choose all that apply

- Indication: □ Active hemorrhage □ Hemorrhagic shock (use of vasopressor) □ At risk for massive transfusion □ At risk of hemorrhage

- Context: □ Severe blunt trauma □ Gunshot wound/explosive □ Obstetrics □ Severe penetrating trauma □ Other (describe):

Date and time of event/injury: / / 20 - H

- Concomitant transfusion (describe): □ Whole blood (No): .... □ Platelets (No): .... □ PRBCs (No): ....
- IV Fluids (type/ml): ..........................................
- Other blood-derived products (type/units):

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- Clinical evolution: □ Favorable □ Stabilization □ Worsening □ Death
- Transfer of patient*: □ NO □ YES (treatment facility):

Name and signature of Physician responsible for transfusion: .................................

Version 11.00.2011
CTSA 1 rue du Li Raoul Benay – 92141 CLAMART Cedex; Tel.: 01.41.46.72.23 - Fax: 01.41.46.72.74

onsdag 5. september 2012
CLINICAL and LABORATORY TRACKING FORM
Freeze-dried Plasma (FDP)

1 Form per Transfusion Episode (T.E.)
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Choose all that apply

- Indication: □ Active hemorrhage □ Hemorrhagic shock (use of vasopressor)
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Date and time of event/injury: ................................ / ....... / ....... 20__ ....... H ...

- Concomitant transfusion (describe): Whole blood (No.): ....... Platelets (No.): ....... PRBCs (No.): ....... ...
- □ IV Fluids (type/amount): ................................
- Other blood-derived products (type/amount): 1 g Tranexamic acid

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Fibrinogen g/L

PT

INR

CLINICAL EVOLUTION AFTER TRANSFUSION OF FDP:

- Clinical tolerance: □ Good □ Adverse event (time from infusion of FDP): ................................
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- Clinical evolution: □ Favorable □ Stabilization □ Worsening □ Death
- Transfer of patient? □ NO □ YES (treatment facility): ................................

Name and signature of Physician responsible for transfusion: ................................

onsdag 5. september 2012
USE OF THE NEW CLINICAL AND BIOLOGICAL SHEET
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USE OF THE NEW CLINICAL AND BIOLOGICAL SHEET

• Global transfusion activity in 2011:
  
  ➢ 445 RBC: 1 – 15 (3,5)
  
  ➢ 205 FLYP: 1 – 24 (average: 2,27)
  
  ➢ 185 FWB: 1 – 18 (average: 4)
  
  ➢ Only fugitive erythema without certitude about its origin (many drugs).
USE OF THE FLYP IN ROLE 1
NEW PACKAGING FOR ROLE 1
USE OF THE FLYP IN ROLE 1
NEW PACKAGING FOR ROLE 1

onsdag 5. september 2012
USE OF THE FLYP IN ROLE 1
NEW PACKAGING FOR ROLE 1
USE OF THE FLYP IN ROLE 1 & ALL MEDEVAC

- All MEDEVAC:
  - Medevac between role 3 and 4
  - Medevac between role 1 and roles 2 or 3.
USE OF THE FLYP IN CIVILIAN

- Supported earliest serious bleeding patients, pending the availability of FFP thawed (within 30 to 90 minutes).
- Logistical conditions "constraints" and difficulties in ensuring a negative cold chain:
  - Emergency services extremely isolated
  - Overseas territories
  - MEDEVAC long distance.
ACKNOWLEDGEMENTS

- Dr. C. Martinaud, Biologist, MYH Percy
- Dr. C. Civadier, Control Department CTSA
- Dr. AV. Deshaye, Production Department, CTSA
- Technicians of the Control Departement CTSA
- Dr. F. Martelet
- Pr. S. Ausset, Anesthesiology Department, MTH Percy

onsdag 5. september 2012
THANK YOU FOR YOUR ATTENTION