Intercept in Lausanne: 6 months experience and future plans

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Agenda

Experience with Intercept platelets
Future plans for Intercept plasma
Annual production in Lausanne

- 30,000 whole blood donations
- 3,000-3,300 platelet concentrates
- 7,000 FFP
- 8,000 liters fractionation plasma
Introduction of Intercept - platelets: technical and strategic choices

• Introduction of Buffy coat pooling for platelet production:
  • release the pressure on aphaeresis donors and staff
  • slight production increase
  • equilibrate Intercept introduction with lower cost platelet production

• Single whole blood collection kit:
  • simplified work at the collection sites

• Single whole blood process:
  • all buffy coats are eligible for platelet production (except AINS)
  • Pools of 5 random BC
  • plasma loss compared to “dry” buffy coats production
Our whole-blood process

BC: Vol=62 mL, Htc=0.4
Advantages of BC pooling

- Buffy coats are always available (given off-site collections take place the day before)
- Having a single collection kit and single whole-blood process allows on-demand modification of production objectives:

![Graph showing modification of production objectives with bars for Buffy coat and Aphaeresis with a trend line indicating high external demand.](chart.png)
Increase of total production

Annual production: 3,600 PC
Plans for Intercept plasma
Background regulatory information

- The Intercept process for plasma was initially approved by Swissmedic in December 2010.

- A revision was submitted to Swissmedic in May 2011 (see below).

- A process similar to the Intercept-platelet approval process is ongoing: Lausanne currently prepares a national validation plan that will be submitted to Swissmedic in cooperation with the “labile Blutprodukte neue Materialien (LPNM)” of the Swiss Red Cross.

- Lausanne (for whole-blood plasma) and Lugano (for aphaeresis plasma) will act as pilot centers for the initial validation of the Intercept process.
## Possibilities of plasma sources

<table>
<thead>
<tr>
<th>Source</th>
<th>Volume Range</th>
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<tbody>
<tr>
<td>Plasmapheresis</td>
<td>Up to 650 mL</td>
</tr>
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<td>Concurrent plasma (PLT apheresis)</td>
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**Intercept plasma kit**

385-650 mL
Possibilities of plasma sources

- **Plasmapheresis**: Up to 650 mL
- **Concurrent plasma (PLT apheresis)**: Approx. 200 or 400 mL
- **Recovery plasma (whole blood)**: Approx. 250-280 mL

- Pool 2 or 3 units
- Intercept plasma kit: 385-650 mL
- Pool 3 units / filter
Next steps

Design of a validation plan

Approval of the validation plan

Validation data

Approval of validation data

Approval of whole-blood pooled plasma
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>Who</th>
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</thead>
<tbody>
<tr>
<td>Submission of the validation plan to Swissmedic</td>
<td>October 2011</td>
<td>Lausanne</td>
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<tr>
<td>Approbation of whole-blood plasma pooling</td>
<td>Fall-winter 2011</td>
<td>Swiss Red Cross- Lausanne</td>
</tr>
<tr>
<td>Validation of whole-blood plasma inactivation</td>
<td>Early 2012</td>
<td>Lausanne</td>
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<tr>
<td>Validation of aphaeresis plasma</td>
<td>Early - spring 2012</td>
<td>Lugano</td>
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<tr>
<td>Dissemination of Intercept plasma</td>
<td>Summer 2012</td>
<td>Those interested</td>
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</tbody>
</table>
Thank you!