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SERVICE RÉGIONAL VAUDOIS DE TRANSFUSION SANGUINE

Intercept in Lausanne: 6 months experience and future plans

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Cerus Symposium at Swiss Transfusion 2011, Fribourg



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Agenda

Experience with Intercept platelets
Future plans for Intercept plasma

Annual production in Lausanne

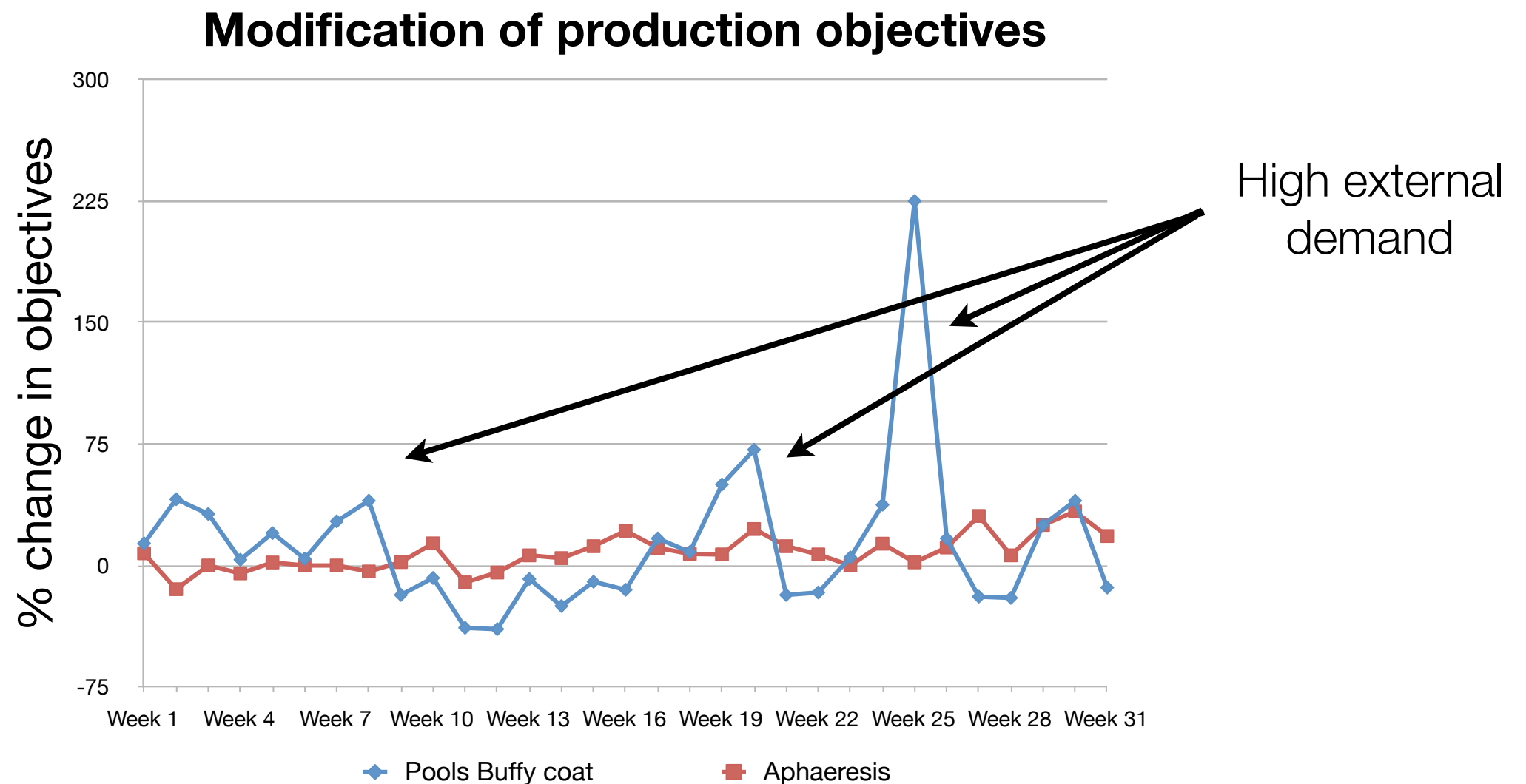
- 30'000 whole blood donations
- 3'000-3'300 platelet concentrates
- 7'000 FFP
- 8'000 liters fractionation plasma

Introduction of Intercept - platelets: technical and strategic choices

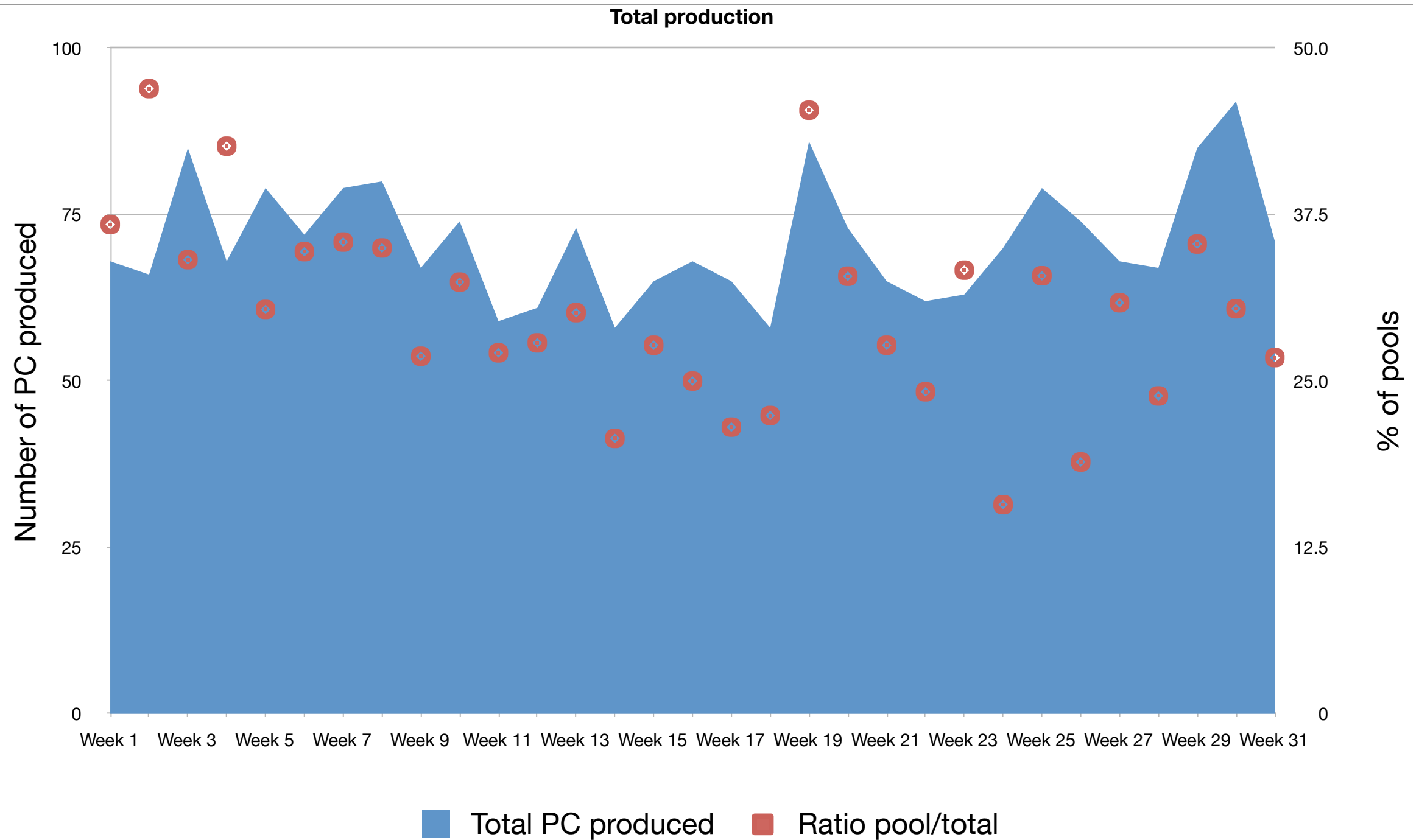
- Introduction of Buffy coat pooling for platelet production:
 - release the pressure on aphaeresis donors and staff
 - slight production increase
 - equilibrate Intercept introduction with lower cost platelet production
- Single whole blood collection kit:
 - simplified work at the collection sites
- 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

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:



Increase of total production



Annual production: 3'600 PC



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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

Plasmapheresis

Up to 650 mL

Concurrent plasma
(PLT apheresis)

Approx. 200 or 400 mL

Recovery plasma
(whole blood)

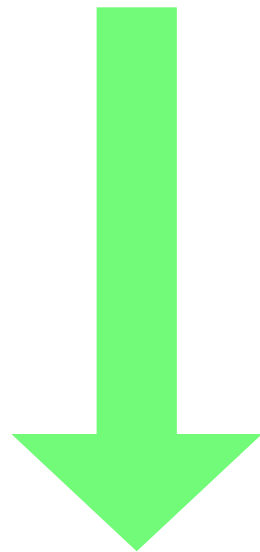
Approx 250-280 mL

Intercept plasma kit
385-650 mL

Possibilities of plasma sources

Plasmapheresis

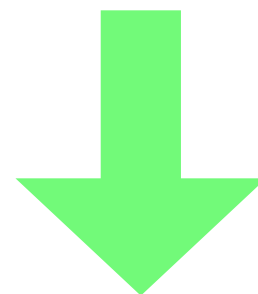
Up to 650 mL



Concurrent plasma
(PLT apheresis)

Approx. 200 or 400 mL

Pool 2 or 3 units

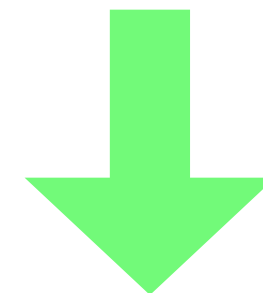


Intercept plasma kit
385-650 mL

Recovery plasma
(whole blood)

Approx 250-280 mL

Pool 3 units
/ filter



Next steps

Design of a validation plan



BLUTSPENDE SRK SCHWEIZ
TRANSFUSION CRS SUISSE
TRASFUSIONE CRS SVIZZERA

Approval of the validation plan



Validation data



Approval of validation data



Approval of whole-blood pooled plasma



To do list

Action	Date	Who
Submission of the validation plan to Swissmedic	October 2011	Lausanne
Approbation of whole-blood plasma pooling	Fall-winter 2011	Swiss Red Cross- Lausanne
Validation of whole-blood plasma inactivation	Early 2012	Lausanne
Validation of aphaeresis plasma	Early - spring 2012	Lugano
Dissemination of Intercept plasma	Summer 2012	Those interested



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Thank you!