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## Canadian Blood Services Product Development – What's in the Pipeline?

*The Future of Blood Transfusion Medicine  
London, Ontario  
Robert Romans, November 8, 2008*


  
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## A **LOOK** back and a **LOOK** forward



  
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## Outline




**Opportunities for the future**

**The product pipeline**

**Canadian Blood Services' change agenda**

**The legacy:**  
Krever Commission provides a system roadmap


  
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## The legacy: Krever Commission provides a system roadmap

  
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## Legacy - born in an environment of failure and scandal



  
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## The Commission of Inquiry on the Blood System in Canada

Federal government determines need for a commission of inquiry

Justice Horace Krever, appointed by Order in Council, October 4<sup>th</sup> 1993


- to review and report on the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada


Justice Krever tables an Interim Report

- February 15<sup>th</sup> 1995
- 43 recommendations focused on operational, technical and clinical aspects of blood system at the time


Work on final report continues

- 247 days of hearings from 474 individuals
- phase I – input from those infected with HIV or HCV
- phase II – national issues concerning historical actions and relationships
- phase III – organization of the blood system at the time
- appeals under *Section 13 of the Inquiries Act* caused significant delays
- final report released November 26<sup>th</sup>, 1997




  
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# Canadian Blood Services' change agenda



# Canadian Blood Services' change agenda

**Transition**

Canadian Red Cross Society to Canadian Blood Services

April – Sept. 1998

**Stabilize**


Gain understanding of major issues  
Determine requirements for change

Approximately 18 months

**Transform**


Re-engineer the system  
Regain trust and confidence in the blood supply

3 – 5 years



## The past years

**Safety**

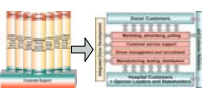


**Security of supply**


Supply Growth Since 1998/1999

Whole Blood	Plasma	FFO	FBO
28%	124%	47%	51%

**Service delivery model**




**Trust**



Public trust in 1998 had fallen to 50%

83%



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# The product pipeline





## Product Development

CBS, Circular of Information 1998

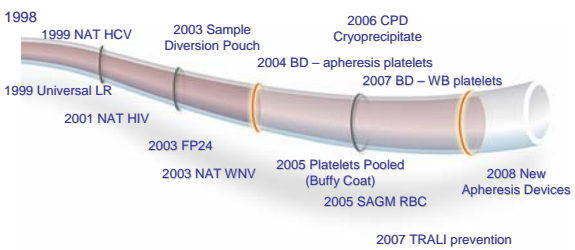


CBS, Circular of Information 2008






## The Product Pipeline



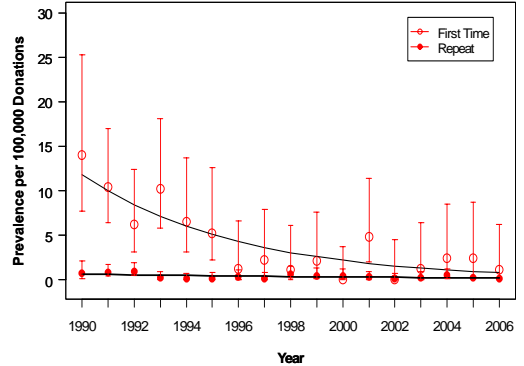
- 1998: 1999 NAT HCV, 1999 Universal LR
- 2001: NAT HIV
- 2003: Sample Diversion Pouch, FP24, NAT WNV
- 2004: BD – apheresis platelets
- 2005: Platelets Pooled (Buffy Coat), SAGM RBC
- 2006: CPD Cryoprecipitate
- 2007: BD – WB platelets, TRALI prevention
- 2008: New Apheresis Devices



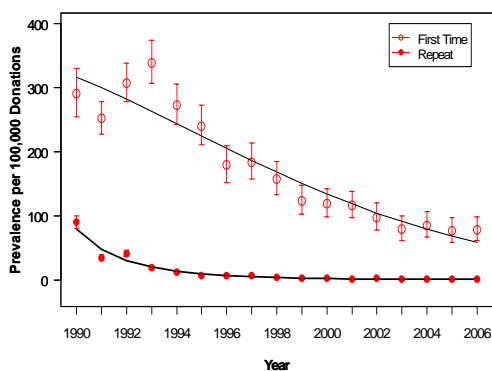
## Viral Safety – Donor Testing

- The last ten years has seen significant changes in our approach to donor screening;
  - Consolidation of testing
  - NAT HCV
  - NAT HIV
  - NAT WNV
  - Anti-HBc
  - Olympus PK7200
  - Abbott PRISM
  - Donor screening questionnaire changes
  - .....to name a few!!

HIV prevalence per 100,000 donations by donation status, 1990-2006



HCV prevalence per 100,000 donations by donation status, 1990-2006



## Bacterial Detection - development

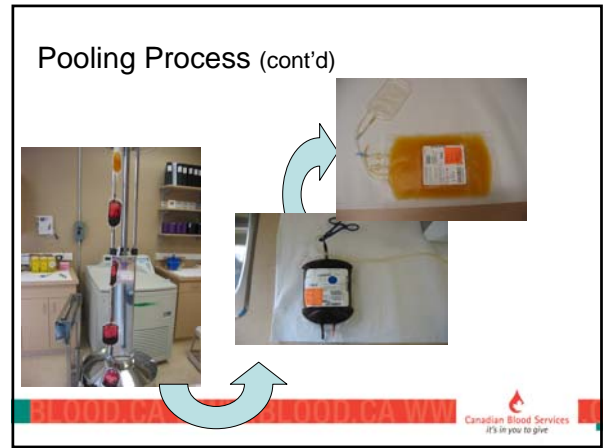
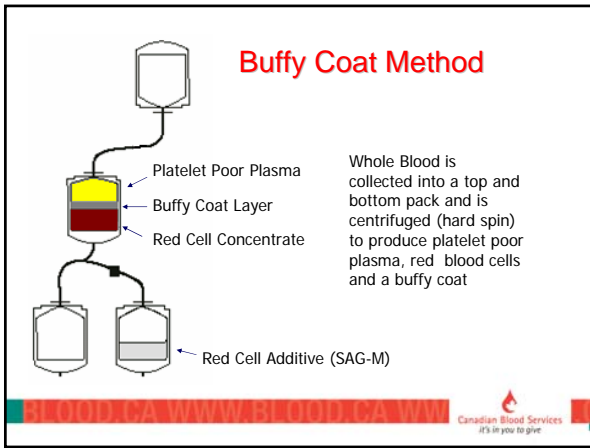
- Skin Disinfection
- Leucoreduction
- Sample Diversion Pouch
- Bacterial Detection – apheresis
- Bacterial Detection – Hong Kong Method
- Bacterial Detection – Platelets, Pooled (Buffy Coat)

## Fresh Frozen Plasma to Frozen Plasma

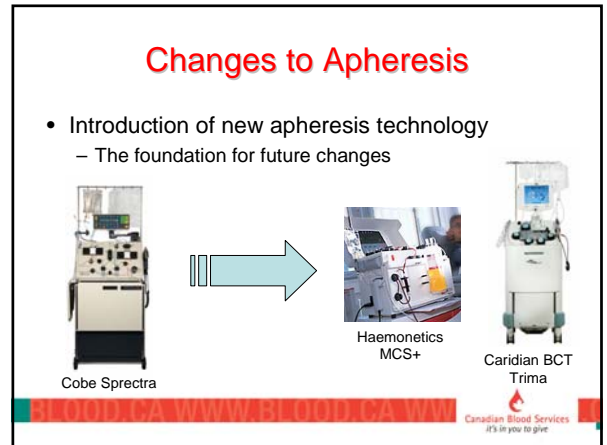
- Transition from preparing plasma for transfusion from plasma processed within 8 hours (FFP) to plasma frozen within 24 hours (FP)
  - Initially to allow for stockpiling of plasma prior to WNV season prior to availability of WNV testing
  - Now it is key to enable sufficiency of supply from a greater number of whole blood collections
    - Since fall 2007 Frozen Plasma production has switched to producing from predominantly male donors – TRALI prevention

## Buffy Coat

- The BC method was developed in the late 1970s and has been widely used in Europe since the late 1980s initially as a means of leucoreducing components.
- Adopted by CBS for other reasons;
  - Increased volume of Recovered Plasma
  - Increase in time allowed for component production (24 hours vs. 8 hours)
  - Reduction in number of pack types (from 8 to 2)
  - Pooled “ready to transfuse” platelet concentrate that is more amenable to Bacterial Detection
  - More consistent recoveries, therefore more consistent platelet dose
  - Increased process control



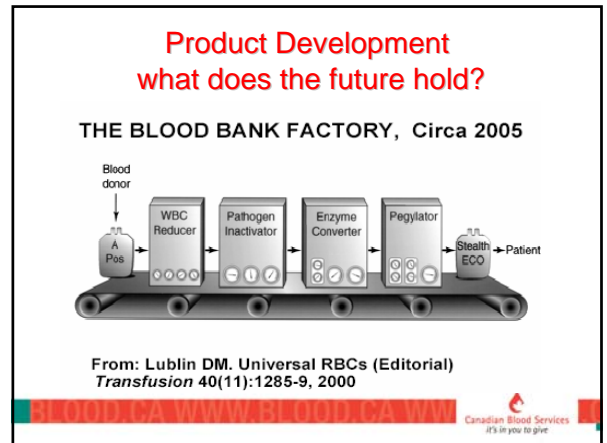
- ## Buffy Coat – add on's
- New red cell additive solution
  - Multiple venter strategy
  - CPD Cryoprecipitate
  - National, standardized processes for;
    - Frozen/Deglyced red cells
    - Washed red cells
    - Divided products
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## Opportunities for the future

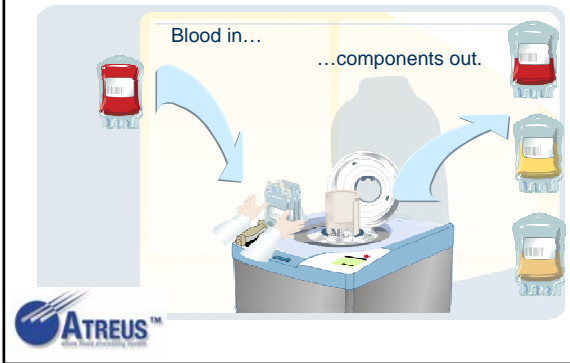
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## Platelet Additive Solution

- Platelet additive solutions (PAS) have been developed in an attempt to improve the quality of platelets over the storage period (reviewed in Murphy, 1999; Gulliksson, 2000; Cardigan and Williamson, 2003).
- PAS generally substitutes for 55-85% of the plasma in a platelet concentrate.
- The four drivers for the adoption of PAS are:
  - To narrow the sufficiency gap for IVIG from Canadian plasma
  - To reduce the incidence of TRALI reactions
  - To reduce the risk of producing platelet products that could potentially contain high titre antibodies to ABO and other antigens
  - To realize production efficiencies

## Further automation in whole blood processing?



## Further automation in whole blood processing?

- Closed system cell washing
  - Could allow for 7-14 day shelf life for washed red cells



## Further Changes to Apheresis

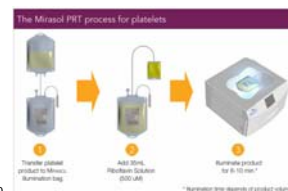
- Introduction of multiple component collections;
- e.g. double platelets, Double red cells



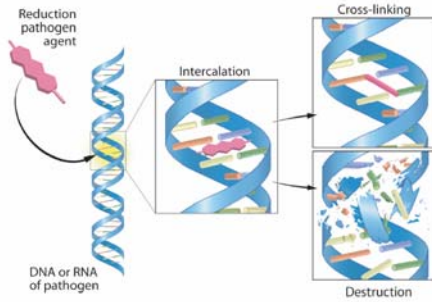
## Pathogen Inactivation/Reduction

- A process for killing living cells including
  - Viruses
  - Bacteria
  - Parasites
- In the blood industry it is an established way to treat fractionated products during manufacture. Progress is being made to apply it to increasing the safety of fresh products (RBCs, platelets, plasma).

## Pathogen Reduction/Inactivation Technologies



## PI Technologies Work by Disrupting Nucleic Acid



## Principal Methods Applied to Components

- | Chemical Inactivation  | Others   |
|--|--|
| <ul style="list-style-type: none"> <li>• Pooled Plasma                             <ul style="list-style-type: none"> <li>– Solvent Detergent (SD, Octaplas)*</li> </ul> </li> <li>• Single Donor Plasma                             <ul style="list-style-type: none"> <li>– S-59 (psoralen)*</li> <li>– Methylene blue*</li> </ul> </li> <li>• Cellular components                             <ul style="list-style-type: none"> <li>– S-59 (psoralen)*</li> <li>– Riboflavin</li> <li>– S-303</li> <li>– Thianine</li> <li>– (Inactine)</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• UV-C inactivation for platelets and plasma</li> </ul> |

\*approved/licensed in Canada

## New lines of business?

- Opportunities in
  - Umbilical cord banking
  - Organs and Tissues
- Public consultations underway

Organ donation and transplantation streamlined in new national system  
Patient/donor registries and \$35 million in new funding will save lives

Ottawa, August 12, 2009 – Federal, provincial and territorial ministers of health announced today a combined investment of \$35 million over the next five years to create an integrated national system to significantly improve organ donation and transplantation in Canada.

Under the new funding arrangement, the Canadian Council for Donation and Transplantation (CCDT) has merged with Canadian Blood Services which has expanded its mandate and activities beyond blood services and into organ and tissue donation and transplantation.



## No attempt was made to cover it all!



## Questions / Comments ?