Vein-to-Vein Virtual Tour

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Camp with the Bank
November 2021

Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Objectives

- Recognize the history and importance of precautionary strategy
- Understand and describe how blood products are manufactured at Canadian Blood Services (CBS)
- Understand and describe how blood is received and transfused into patients in the hospital
- Consider resources and cost in blood transfusion policy and patient care decision-making

Tragedy

After being transfused blood between late 1970s and 1980s

- **1,200 infected with HIV**
- **60,000 infected with hepatitis C**

“Arguably the largest public heath catastrophe in the country’s history”

-Picard, A. The Gift of Death 1995

The Krever Inquiry

- The Commission of Inquiry on the Blood System in Canada (known as the Krever Inquiry) was commissioned by the Federal Government in October 1993
- Headed by Mr J
  - *~Four years*
  - *Final report c*
  - *Legal battles* *ublicly* *those who ha*
- Redefined the r al framework that i
- One of its most rofile public inquiry, almost $10 billion in legal claims and a criminal investigation

> *In retrospect, the findings of the Krever Commission could perhaps be considered the most influential report on public health in Canadian history. The report and the success of the reformed blood system provide important lessons related to public health.*
>
> *-Wilson CMAJ 2007*

Decisions & Non-Decisions

- Early in the AIDS epidemic, failure to screen out high-risk donors
- Importation of plasma collected in US prisons and in high-risk areas like San Francisco at the height of the AIDS epidemic
- Delays in purchasing safer, heat-treated blood products for hemophiliacs prompted by a desire to use up inventory of contaminated products
- Delays in implementation of testing for the AIDS virus due to spending restrictions

Decisions & Non-Decisions cont.

- Refusal to use a test that would have identified ~ 90% HCV
- Once tragedy became known, a failure to track down those who had received tainted blood so they could receive treatment and avoid passing on the viruses to others
- Destruction of key documents
- Denial of compensation to infected claimants
- Refusal of the Red Cross and provincial and federal ministers to apologize

Krever Recommendations

1. Compensate victims
2. Safe, Free, Sufficient, Accessible
3. Single, public, open, independent operator
4. Promote appropriate use of blood products
5. Funded by hospitals
6. Creation of a national database
7. 10% of funding for research
8. Mandatory reporting of adverse events

Krever H. The blood supply system in Canada: systemic problems in the 1980s. *Commission of Inquiry on the Blood System in Canada. Final report.* Ottawa: Canadian Government Publishing; 1997;989

"...action to reduce risk should not await scientific certainty. When there was reasonable evidence that serious infectious diseases could be transmitted by blood, the principal actors in the blood supply system in Canada refrained from taking essential preventive measures until causation had been proved with scientific certainty. The result was a national public health disaster."

Krever H. The blood supply system in Canada: systemic problems in the 1980s. *Commission of Inquiry on the Blood System in Canada. Final report.* Ottawa: Canadian Government Publishing; 1997;989.

Estimated numbers of persons with haemophilia alive in 2007 and infected with HCV, HIV and related compensation

Country (number of persons with haemophilia)	Number of persons with haemophilia alive today with HCV or HIV		Year of publication of report from official public inquiry into viral contamination of the blood supply		Approximate average award from national compensation fund (year compensation fund established)	
	HCV	HIV[a]	HCV	HIV	HCV	HIV
USA (14 886)	4456	1698	None	1995	None	$125 000 (1995)
UK (6109)	2829	405	Scotland only (2000)	None	$36 000 (2004)	$37 000 (1988)
Italy (5319)	4361	534	None	None	None[b]	None[b]
Japan (4683)	2436	871	None	None	None	$375 000 (1996)
France (4000)	2600	1250	None	1991	None	$150 000 to $400 000 (1991)
Canada (2772)	1100	251	1997	1997	$50 000 (1989)	$160 000 (1991)
Australia (1070)	534	84	2004	None	Some assistance with medical care	$39 000 (1989)
Ireland (545)	157	37	1997, 2002	2002	$36 000 (1997)	$46 000 (2002)

[a]Actual number of persons with haemophilia infected with HIV is larger than the numbers living today, but many have since died of AIDS-related complications.
[b]Compensation was recommended but not paid.

Blood Services ORGANS & TISSUES

Angelotta et al. Vox Sanguinis (2007) **93**, 159–165

A NEW Beginning: Rebuilding Broken Trust

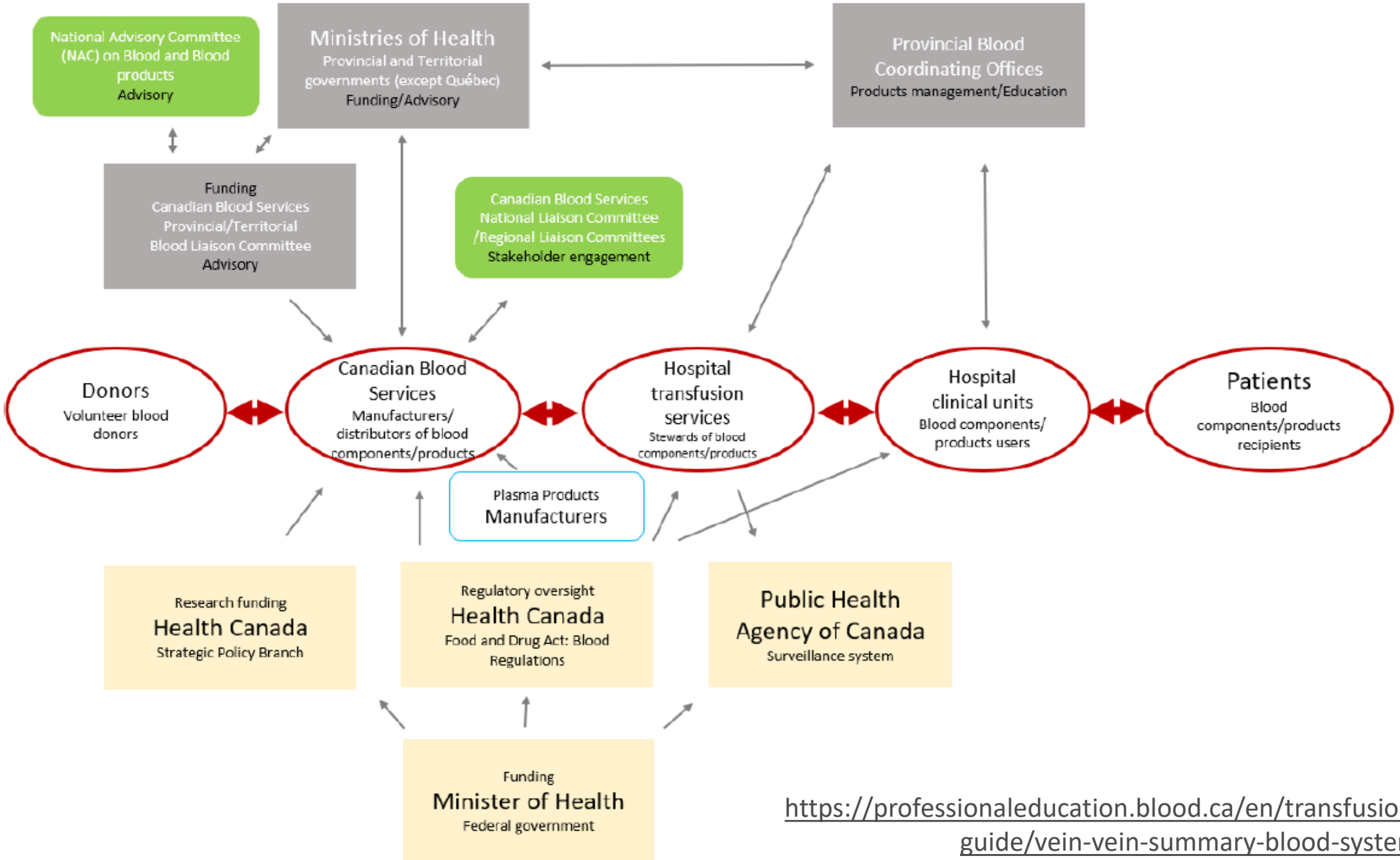
From reactive to proactive

Precautionary Principle

- "Rio" definition:
  - *"where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*
    - *(United Nations Environmental Programme [UNEP] 1992)*
- "Wingspread" definition:
  - *"when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically"*
    - *(SEHN 1998)*

The Blood Services Landscape in Canada

- **Canadian Blood Services** and **Hema-Quebec**
- Highly structured, organized, not-for-profit biologic manufacturers
- Health Canada regulated as a drug



https://professionaleducation.blood.ca/en/transfusion/clinical-guide/vein-vein-summary-blood-system-canada

CBS: Celebrating 20+ Years

- Blood supply in provinces and territories outside of Quebec
- Trusted, respected and valued leader in Canadian health care extended beyond blood and blood products:
  - *One of the safest blood systems in the world*
  - *Stem cell registry*
  - *National public umbilical cord blood bank*
  - *Renewed focus in education, research and innovation*
- Focused on rigorously maintaining the safety and effectiveness of products and services while improving productivity and efficiency

Implementation Measures

- Donor selection/deferral criteria
- Donor testing
- Post Donation Information
- Look back
- Trace back
- Assessing Risk of Emerging Threat; Pathogen Inactivation

Total Budget FY 2020/2021 ($ million)

Total Budget	$1,262.5
Fresh Blood Products	$431.6
Plasma Protein Products	$774.0
Stem Cells (including HLA and Cord)	$31.5
Organs and Tissues	$8.2
Diagnostic Services	$17.2

Canadian Blood Services - Contributors

- > 500 facilities
- > 4,000 employees
- > 17,000 volunteers
- Donors are all voluntary
- > 400,000 donors donated FY19/20
  - *50% male*
  - *Donation frequency: Overall 1.9, Male 2.2, Female 1.6 donations/yr*
- > 450,000 potential stem cell donors
- > 3,600 cord blood units listed for transplant

Red Blood Cells Distributed

Product	Units FY 20/21	Cost / Unit FY 18/19
Red Cells	691,762	$422

Platelets Distributed

Product	Units FY 20/21	Cost / Unit FY 18/19
Total Platelets	113,409	
Apheresis	30,432	$504
Buffy Coat Pool	82,977	$178

Plasma Distributed

Product	Units FY 20/21	Cost / Unit FY 18/19
Plasma for Transfusion	97,210	*$108
Plasma for Fractionation	555,555	NA

*Cost for whole blood plasma unit

Question

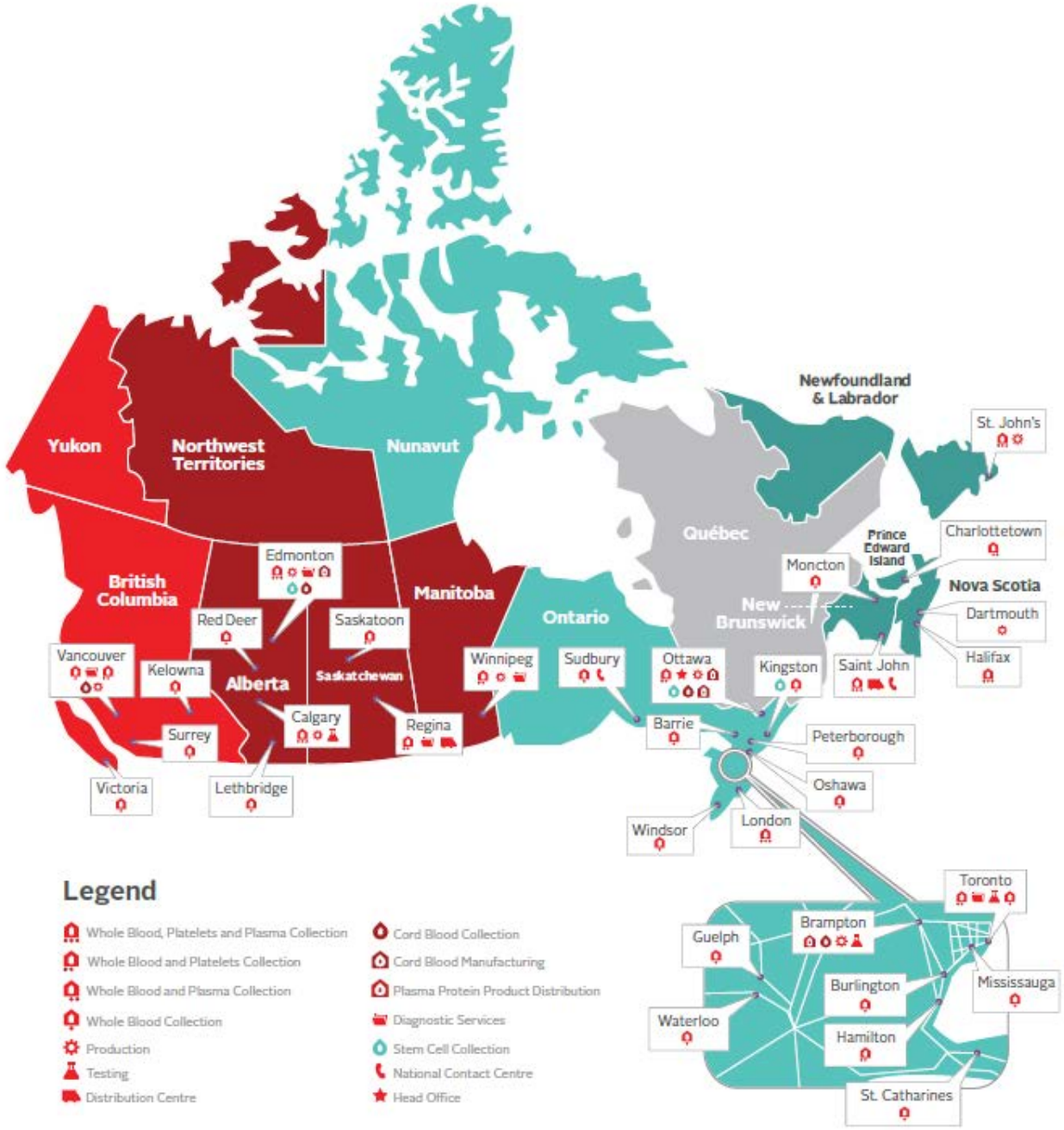
Which is true regarding the cost of blood in Canada

A. The majority of the budget for Canadian Blood Services goes to producing components intended for direct transfusion to patients

B. Blood products are free in Canada

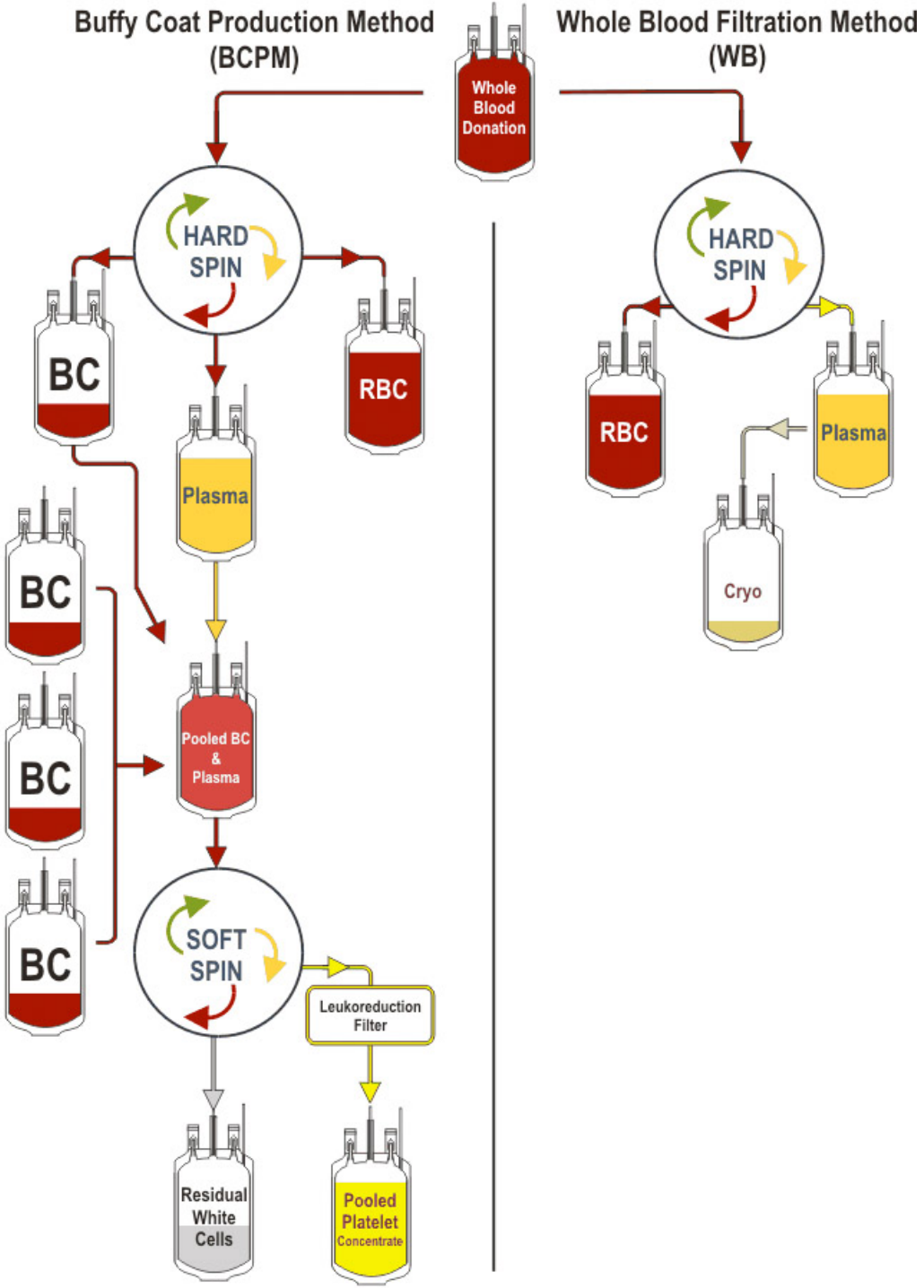
C. Buffy coat platelets are significantly more expensive to produce than are apheresis platelets

D. The majority of the budget for Canadian Blood Services is spent on plasma protein products drugs rather than for transfusion



Canadian Blood Services National System

2019-02-22



Blood and blood component manufacturing process

Filled Whole Blood Collection Pack

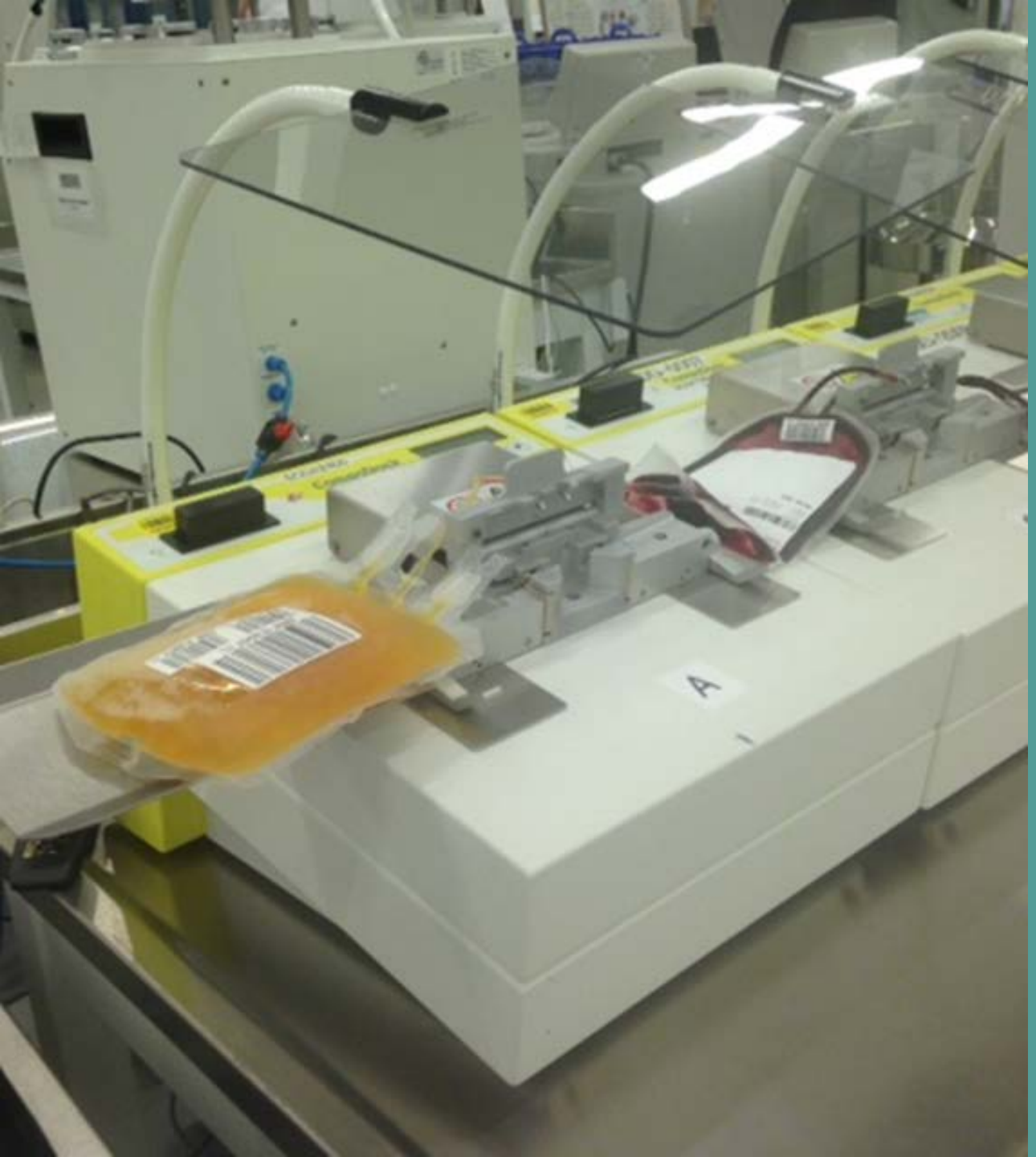
Whole Blood Leukoreduction by Gravity

Separation Pod and Centrifuge

Whole Blood Component Separation

Component Separation

Component Separation



Buffy Coat Units from 4 Donors Connected in Series

Buffy Coat Units Pooled by Gravity

Pooled buffy coats re-spun then platelets decanted with plasma

Irradiated Products

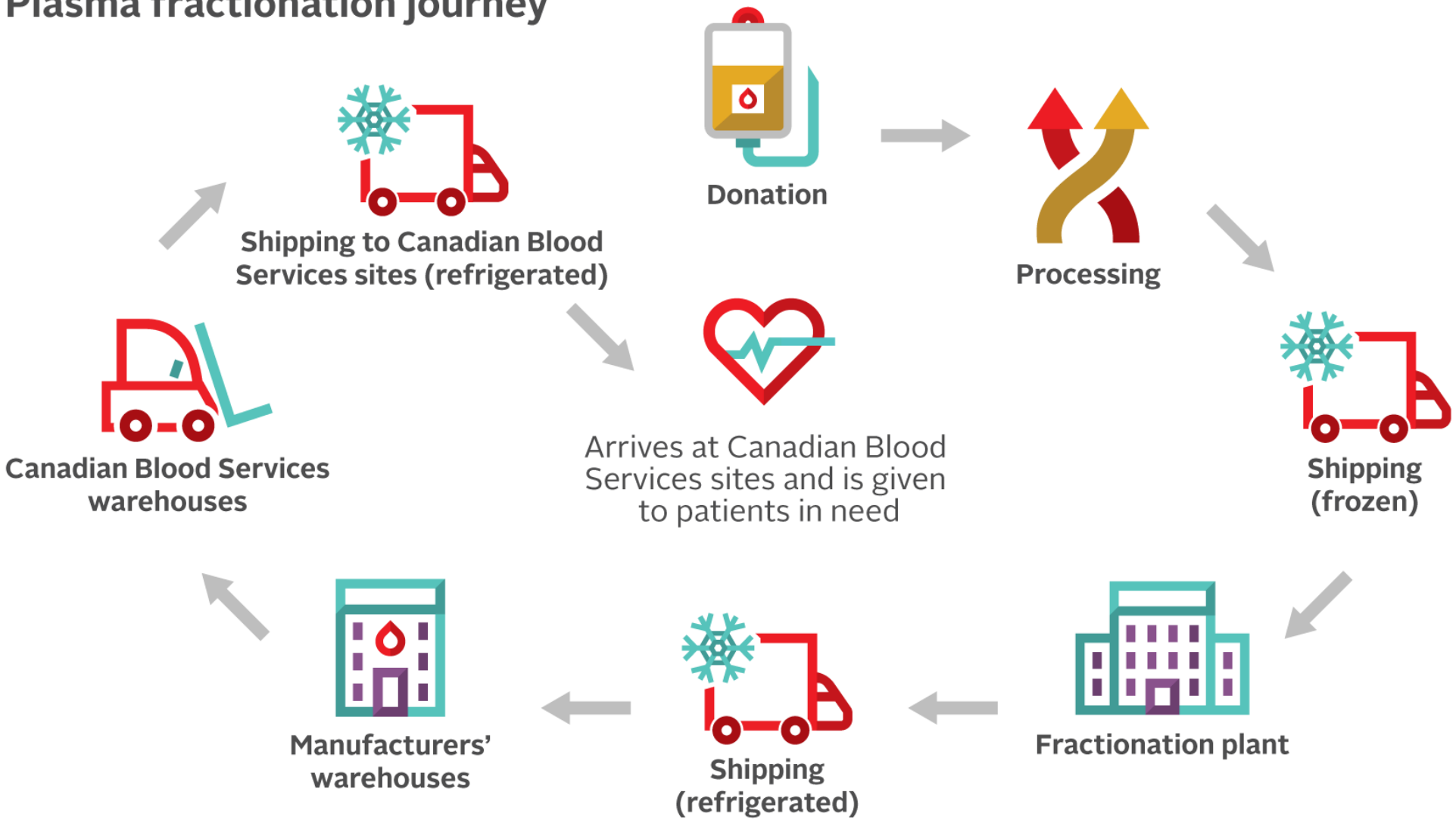
To Prevent TA-GvHD

May irradiate up to 28 days post collection

Impact on RBC expiry:

14 days post-irradiation or 28 days post collection, whichever comes first

Plasma fractionation journey



Fractionation: occur outside of Canada

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https://www.linde-engineering.com/

Canadian Plasma for Protein Drugs

- Canadian plasma provides:
  - *Less than 50% of the demand for albumin in Canada*
  - *Less than 15% of the demand for IVIg in Canada*
  - *Remainder purchased off the open market*
  - *Health Canada approved with excellent safety profiles*

Blood and Products are Shipped to Hospital Blood Banks

Zeller 2021

Hemovigilance

Post Donation Information (PDI)

Lookback/Traceback

Adverse Transfusion Reaction (ATR)

Post Donation Information

- We instruct donors to call if health status changes after donation
- Donors call National Contact Center
- New information on screening that pertains to previous donations
- If new information suggest donor was not eligible previously, or if there is a risk to recipients, we will retrieve blood components
- Notification to blood bank whose medical director may reach out to transfusing physician to discuss possible recipient notification

Lookback / Traceback

- Lookback: Donor with new risk information leading to recall of previously donated products
- Traceback: Patient with new illness after transfusion leading to investigation of all donors from whom patient received blood products

Adverse Events / Transfusion Reaction

- Reactions where a feature of the product appears to be the cause should be reported to the blood center
  - *Septic reaction from bacterial contamination, TRALI*
  - *Not TACO, febrile non-hemolytic transfusion reaction*
- Will retrieve in-date co-components
- Can defer donors that represent a risk to recipients

Question

Which is true regarding maintenance of blood safety in Canada

A. Septic transfusion reactions should be reported to the blood center as there are likely co-components on the market that could be affected

B. Blood centers no longer support investigations into possible viral seroconversions in transfusion recipients

C. Blood centers randomly test up to 25% of donations for infectious diseases prior to release

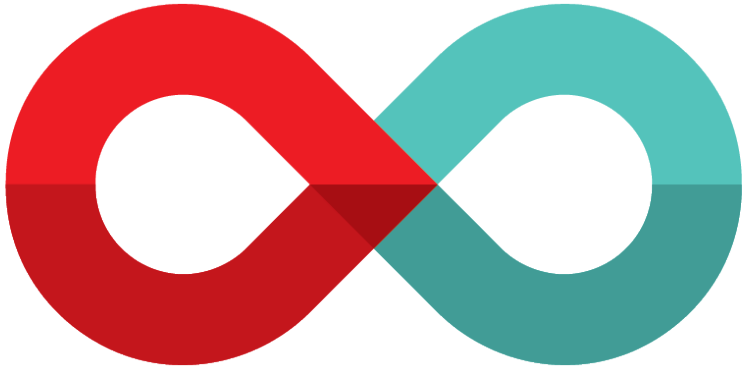
D. If a donor calls to report becoming ill after donation, the blood center has no way of identifying and retrieving the donated units

Summary

- Transfusions carry risk - adverse events should be reported so appropriate steps can be taken with products and donors
- Out of a dark period in the history of Transfusion Medicine in Canada came the establishment of CBS & HQ
- Through rigorous emphasis on safety, efficacy, accessibility, innovation, education and research Canada has one of the safest blood supplies in the world
- It is incumbent on all of us to ensure judicious use of blood
  - *Precious*
  - *Limited*
  - *Life altering – hopefully for good…*

Thank you!

Questions & Comments Welcome



Canadian Blood Services

BLOOD
PLASMA
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