

Canadian Blood Services: Securing the Canadian Plasma Supply for Ig

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Canadian Blood Services

it's in you to give

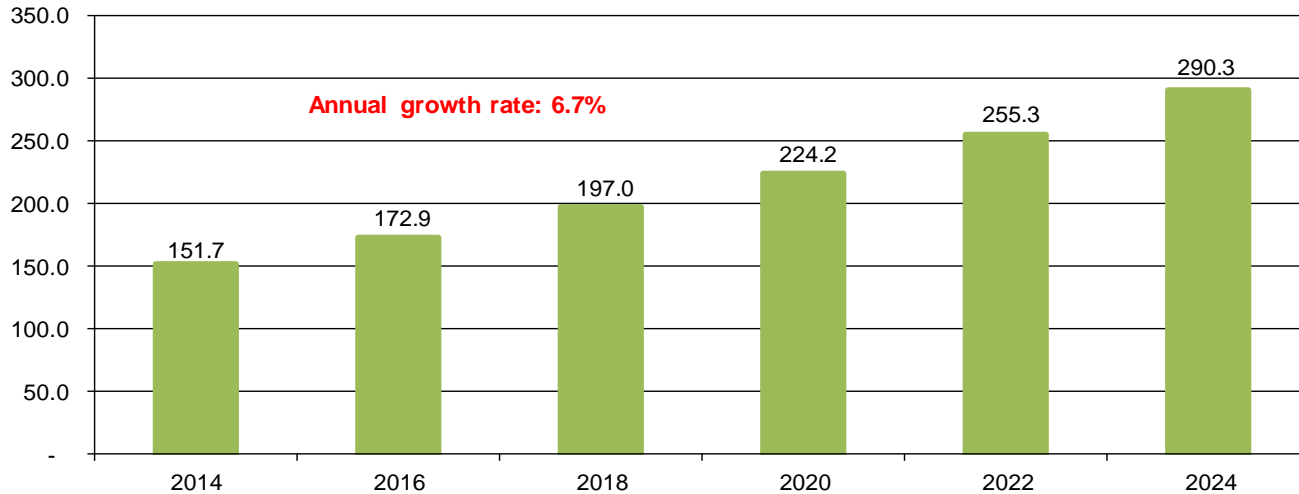
Ig supply and demand trends



Ig supply and demand trends

Global forecast

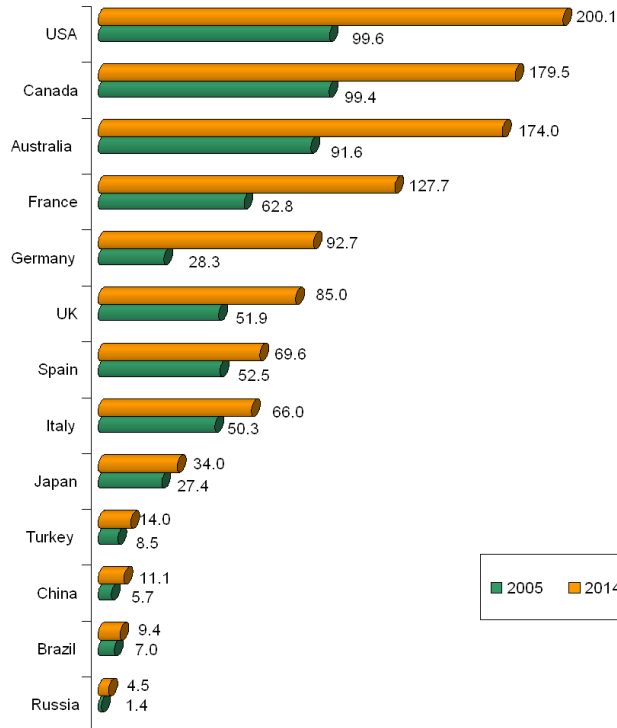
THE WORLDWIDE POLYVALENT IgG MARKET
FROM 2014 TO 2024
(Metric tons)



Ig supply and demand trends

International demand

INTRAVENOUS/SUB-CUTANEOUS (IVIG/SCIG) CONSUMPTION BY COUNTRY
(Kilograms per Million People)

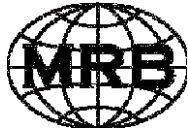


International demand

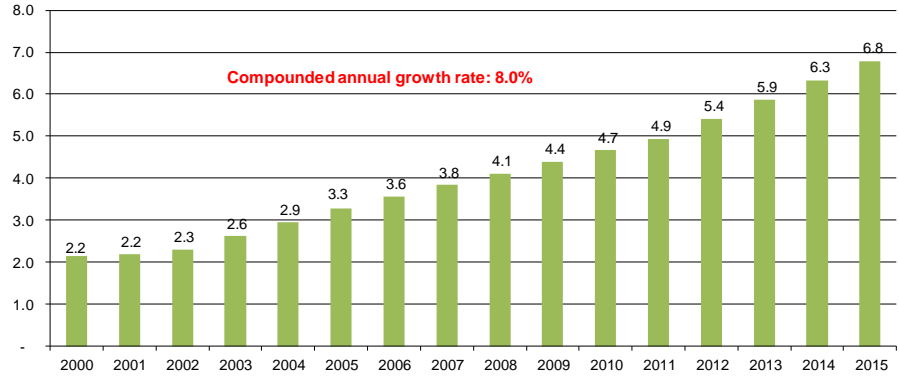
- By 2020 **worldwide demand for Ig will have doubled** over 10 years
- Up to 50 million litres of plasma will be required annually to meet demand — a **40% increase** in plasma fractionated in 2013
- 80% of world's plasma collection sites are in the U.S.
- Great uncertainty over ability of U.S. plasma suppliers to continue to meet demand

Ig supply and demand trends

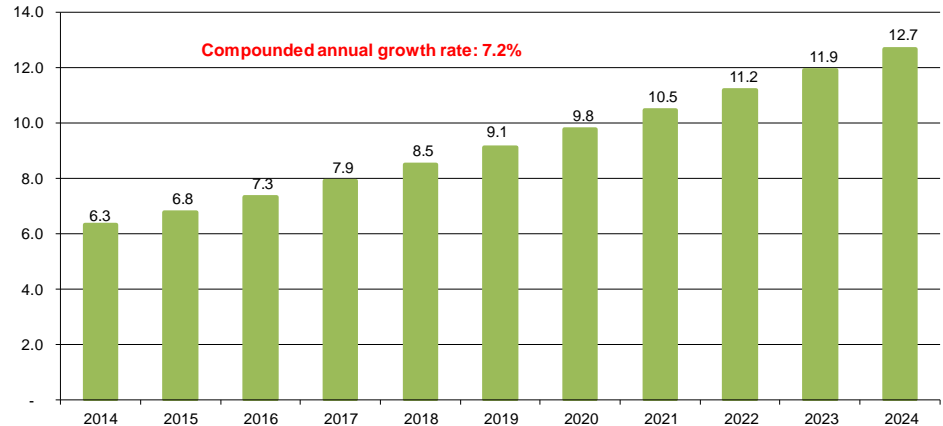
Historical and forecast data for Canada



THE CANADIAN POLYVALENT IgG MARKET
FROM 2000 TO 2015
(Metric tons)



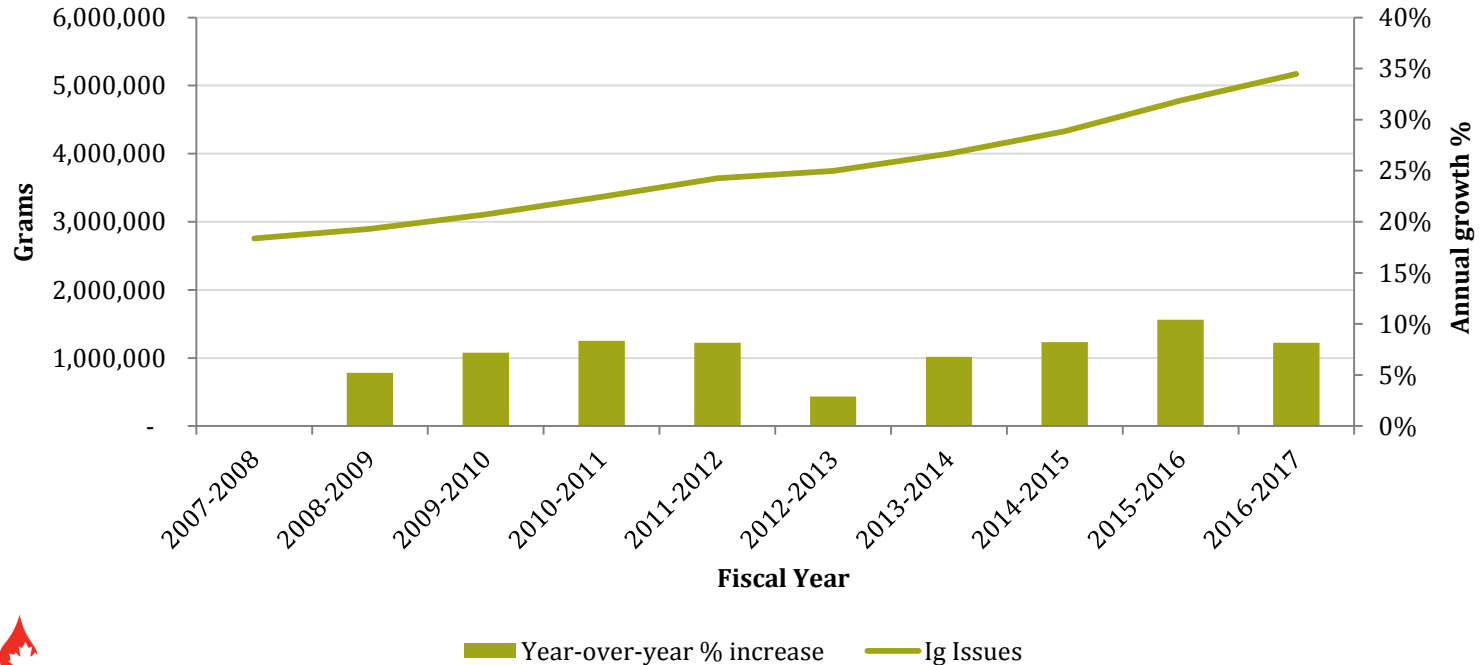
THE CANADIAN POLYVALENT IgG MARKET
FROM 2014 TO 2024
(Metric tons)



Supply and demand trends

Use of Ig in Canada

5.17 million grams in 2016-2017 (excludes Quebec)



Ig supply and demand trends

Canada: Ig Patient population estimates

Specialty	Indication	Dosage & Frequency*	Ig Volume (g) 2015-16	# Patients
Immunology	PID***	Adult: 0.4-0.6g/kg every 4 weeks Pediatric: 0.3-0.6g/kg every 4 weeks	871,000	2,600
	SID	0.4-0.6g/kg every 4 weeks	474,000	1,100
Neurology	CIDP	2g/kg over 2-5 days; maintenance dose: 1g/kg every 3 weeks for ~3 months	841,000	2,200
	MG	2g/kg over 2-5 days; additional therapy as req'd	380,000	2,000
	MMN	2g/kg over 2-5 days; maintenance dose: 1g/kg every 4 weeks	337,000	340
	Guillain-Barre Syndrome	2g/kg over 2-5 days; repeat treatment as req'd	121,000	650
	Connective Tissue Disorder	1g/kg every 4 weeks; variable duration of therapy	50,000	60
	SPS	2g/kg over 2-5 days; additional therapy as req'd	51,000	50
Hematology	ITP	Acute: 1g/kg single dose Chronic: 1-2g/kg	569,000	1,300

Decision Resources Group, 2016-2021 Ig Forecast for Canada

Ig supply and demand trends

Canada: Projected growth rates by indication

Specialty	Indication	% Ig Per Indication ¹	Growth Rate ²
Immunology ~30% of Ig	Primary Immune Deficiency (PID)	60%	11.7%
	Secondary Immune Deficiency (SID)	33%	15.0%
	Other ³	8%	11.5%
Neurology ~41% of Ig	Chronic Idiopathic Demyelinating Polyneuropathy (CIDP)	43%	16.0%
	Myasthenia Gravis (MG)	19%	12.5%
	Multifocal Motor Neuropathy (MMN)	17%	11.0%
	Guillain-Barre Syndrome	6%	1.3%
	Connective Tissue Disorder	3%	11.0%
	Stiff Person Syndrome (SPS)	3%	1.3%
	Other	10%	11.0%
Hematology ~13% of Ig	Idiopathic Thrombocytopenia Purpura (ITP)	89%	2.3%
	Other	11%	2.3%

Decision Resources Group, 2016-2012 Ig Forecast for Canada

Utilization

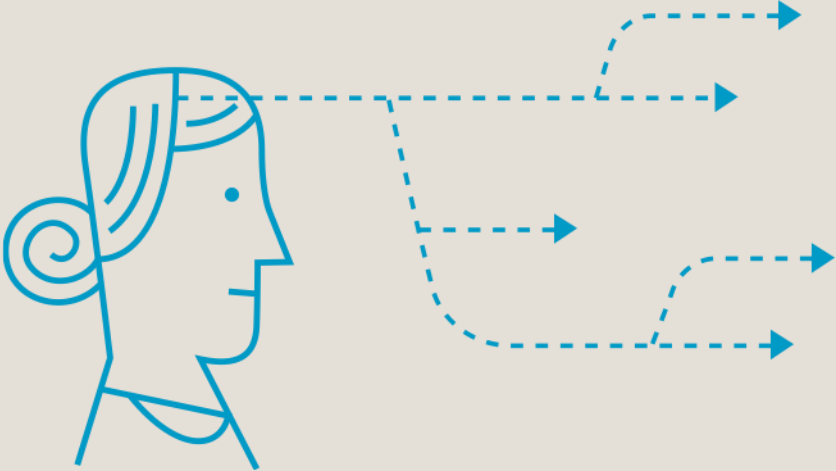
- While “gatekeeping” models may prevent inappropriate use, there is growing recognition that the **growth in Ig utilization represents increased use for approved indications, rather than increased inappropriate use**
- Restricting use to appropriate indications may not lower demand for Ig products in the future
- Significantly restricting or rationing Ig use for appropriate indications would likely lower demand

Canada: Ig utilization

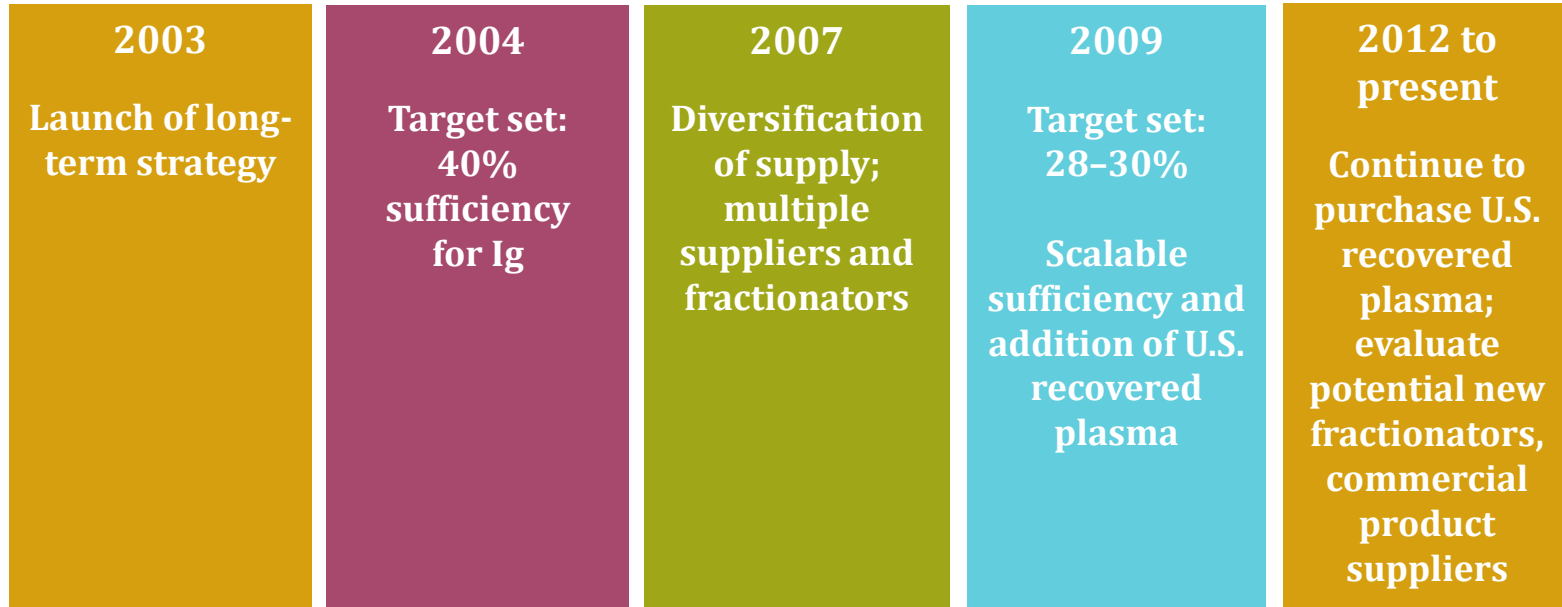
- Many provincial blood offices have initiatives designed to decrease inappropriate or unapproved Ig utilization
- Combined impact over many years has likely contributed to decreased use of Ig for indications considered to be inappropriate or unapproved (~3–11% of total use)
- However, **utilization has continued to increase**, even in provinces with well established “gatekeeping models,” e.g., B.C. and Atlantic Canada

Using less is not the only answer; we need to collect more to make more.

Canada's response



Establishing sufficiency for Canada



Considerations

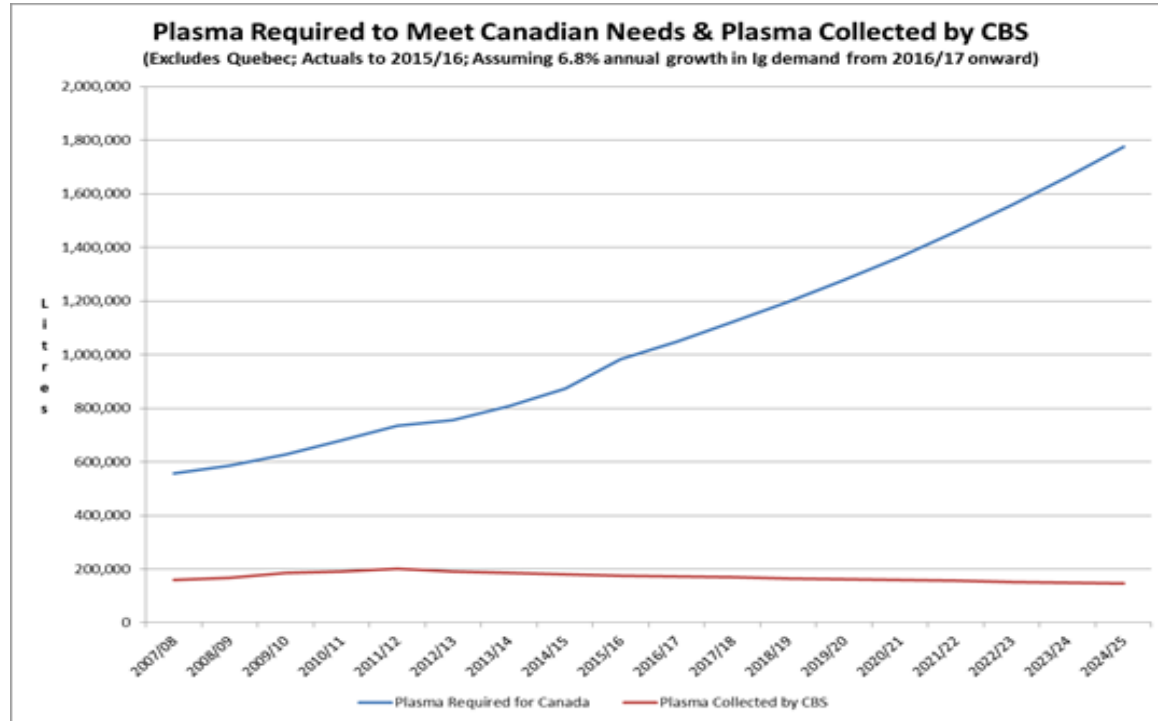
- 100% sufficiency not pragmatic and riskier than diversified approach
 - “All eggs in same basket”: variant Creutzfeldt-Jacob Disease (vCJD) experience in U.K.
 - Interruptions to supply of domestic products in Canada
- Canada has never been self-sufficient in plasma for plasma protein products

Canada's plasma sufficiency for Ig is now about 16%.

At current Ig demand growth rates, Canada will be dependent on U.S. for 90% of its Ig needs in 2023–2024.

International and domestic response

Plasma required and plasma collections



Why 50%?

- In the U.K., the Department of Health published *Clinical Guidelines for Immunoglobulin Use*, updated July 2011.
 - Colour-coded prioritization of Ig treatment during supply shortages
 - Considered availability of alternative treatments and strength of clinical evidence:
- **“Red (category) indicates conditions for which treatment is considered the highest priority because of a risk to life without treatment. The intention remains that Trusts will protect supply for these high-priority diseases in times of immunoglobulin shortage, particularly for patients with primary immunodeficiencies.”**



International and domestic response

Grams Ig used for major priority (red category) indications in U.K. - Comparison with Australia and Canada			
Indication	Grams		
	U.K.*	Australia**	Canada***
Primary immunodeficiencies (PID)	1,102,219	614,781	871,000
Chronic inflammatory demyelinating polyneuropathy (CIDP)	859,480	974,258	841,000
Idiopathic thrombocytopenic purpura (ITP)	222,817	187,621	569,000†
Guillain-Barré syndrome (GBS)	142,456	105,567	121,000
Combined four indications (PID+CIDP+ITP+GBS = A)	2,326,972	1,882,227	2,402,000
Total Ig usage in reference year (B)	4,400,000	4,430,000	4,781,062
Percentage used for priority indications (A/B)	53%	42%	50%
*U.K. NHSBT ; **National Blood Authority (Australia); ***Canadian Blood Services			
† Includes both adult and pediatric use. Australian data includes adult use only and U.K. data is acute use only.			

Risk-based decision-making analysis

- Undertook risk analysis to determine effective, proportional and pragmatic response to system risks
- Completed according to comprehensive requirements of Risk-Based Decision-Making Framework for Blood Safety

Ensuring security of the Canadian plasma supply for Ig: Business plan



Principles (Krever)

- Blood is a public resource
- Donors should not be paid
- Sufficient blood should be collected so that importation is unnecessary
- Access to blood and blood products should be free and universal
- The safety of the blood supply system is paramount

Future plasma collections

- **30 to 40** plasma collection centres across Canada
- **144,000** plasma donors
- **866,000** units or 600,000 additional litres of plasma
- **3 million** additional grams of Ig made from Canadian plasma —
50 per cent of Canada's needs
 - Other 50 per cent of Ig supply = commercial Ig purchased from U.S. suppliers, made from U.S. plasma

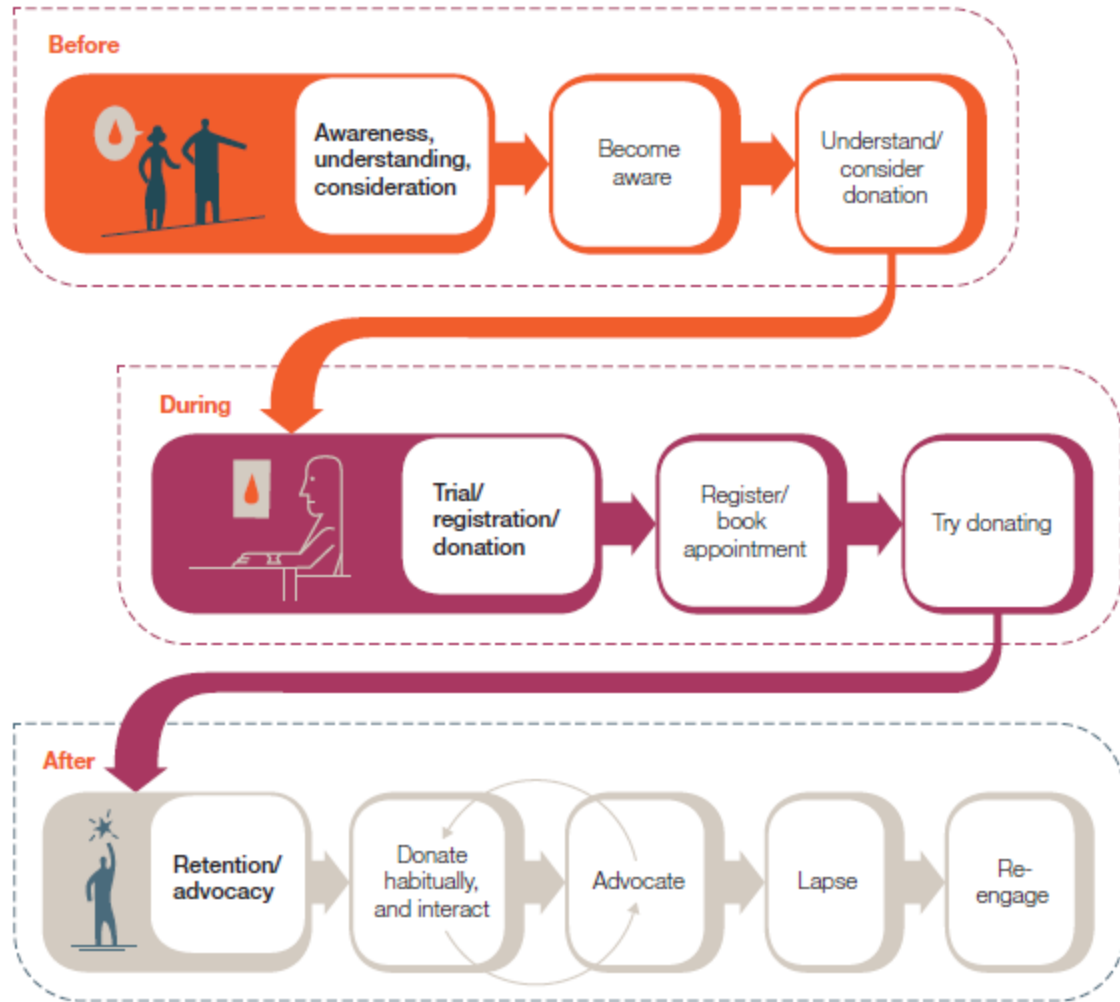
Donor recruitment, selection and testing

- Integrated approach to optimize donors across product lines
- Donor rewards, but not payment — maintaining voluntary, non-remunerated system
- Whole blood and target plasma donors — demographic similarities?
- Streamlined donor selection and testing per regulations and PPTA standards

Ensuring Canadian security of plasma supply for Ig

Recruitment phases

- **Before phase:** Build awareness and interest within immediate catchment area
- **During phase:** Convert prospects into donors
- **After phase:** Retain donors



Collection sites

- Extensive modelling of locations and sizes
- Consistent with our changing blood collection footprint; responsive to increased urbanization of Canada and changing donor demographics
- Mostly co-located with whole blood collection sites; a few stand-alone plasma collection sites
- Focus on urban markets; sites in most provinces
- 6-, 12- and 18-bed sites
 - 12- or 18-bed sites in major urban centres
 - 6- or 12-bed sites in other cities and smaller communities
- Sites branded, owned and operated by Canadian Blood Services

Challenges and opportunities

- Will require expanded outreach; recruitment in the absence of payment
- Striving for efficient operating model — equipment, logistics, layout, processes, etc. — to improve productivity and maintain sustainable cost structure
- A comprehensive, multi-year plan has been submitted to governments and is being reviewed

Threats to blood and plasma collection



Commercial, for-profit plasma collection

Canada: Early impacts

- No clear indicators of new commercial plasma clinics impacting whole blood collections
- Fluctuations in 17-to 24-year-old donor segment observed, but no sustained trend yet
- Heightened vigilance and ongoing monitoring required

Commercial, for-profit plasma collection

Provincial legislation banning paid plasma donation

- Long-standing law (1991) in Quebec prohibits payment for plasma donation
- Ontario passed the *Voluntary Blood Donations Act* in 2014, banning payment for blood or plasma donation, in response to a private pay-for-plasma collector setting up clinics
- Alberta passed legislation similar to Ontario law in 2017

Long-term security of supply can only be achieved through increased plasma collection within the national, not-for-profit system.

Next steps



Next steps

Ensuring a secure supply of plasma for Ig for Canadians

- Risks to security of supply must be addressed
- Ongoing discussions with governments
- Incremental, multi-year approach



Canadian Blood Services
it's in you to give