

Plasma Dynamics in Canada: A Confluence of Perspectives and a Public Sector Solution to Security of Supply

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June 15, 2018



Who we are

Canadian Blood Services

- Independent, non-profit, charitable corporation
- Arm's length from governments
- National, integrated service
- Biologics manufacturer regulated by Health Canada
- Collaborative, pan-Canadian, cost-shared model

Our business by the numbers

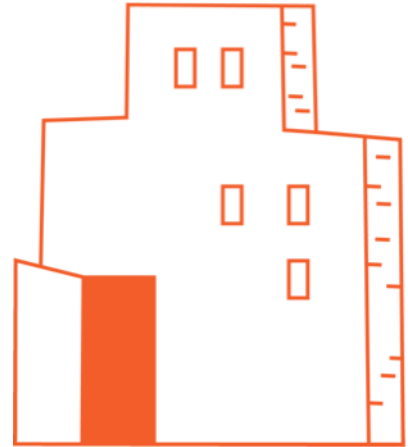
- **400** communities with blood donation sites/events
- **600** hospitals served
- **808,000** units of blood collected in 2017
- **320** stem cell transplants facilitated to date
- **800** kidney transplants facilitated to date
- **4,300** employees
- **17,000** volunteers
- **810,000** blood, plasma, platelet and organ donors and stem cell registrants
- **\$1.2B** annual budget

Who we are



Our role

- Ensure **safety and security of blood system** in Canada on behalf of provincial and territorial governments (corporate members) and Canadians
- Compelling need for **significant plasma expansion** in Canada



Canadian Ig supply and demand trends



Demand trends

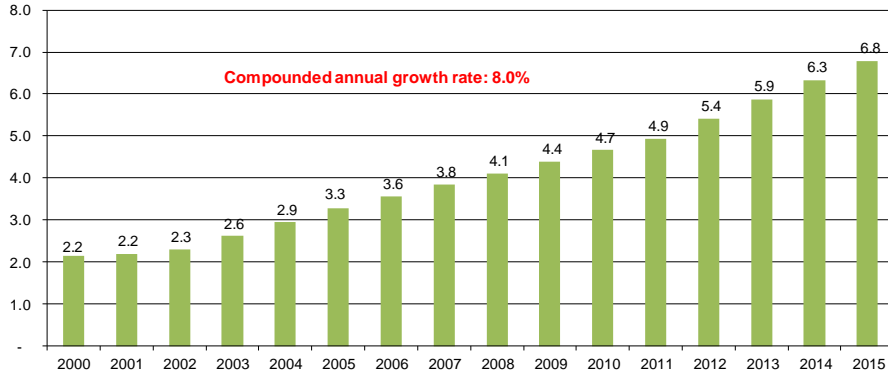
By 2020, worldwide demand for Ig will have doubled over 10 years.

- Up to 50 million litres of plasma will be required annually to meet demand
- 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 due to various risks to supply: infectious disease, political/military factors, geological/climate disaster, new markets (e.g., Chinese market opening to imported IVIg)*
- In Canada, there is an increase in Ig usage of about 7% annually

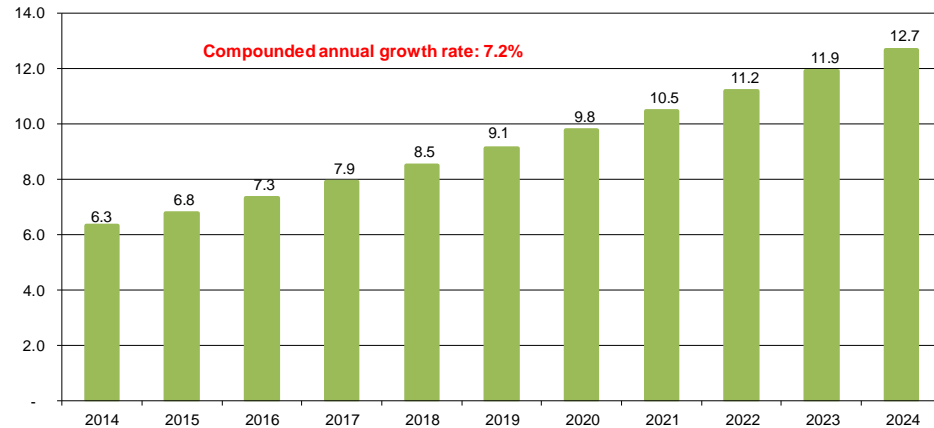
Ig supply and demand trends

Historical and forecast data for Canada

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



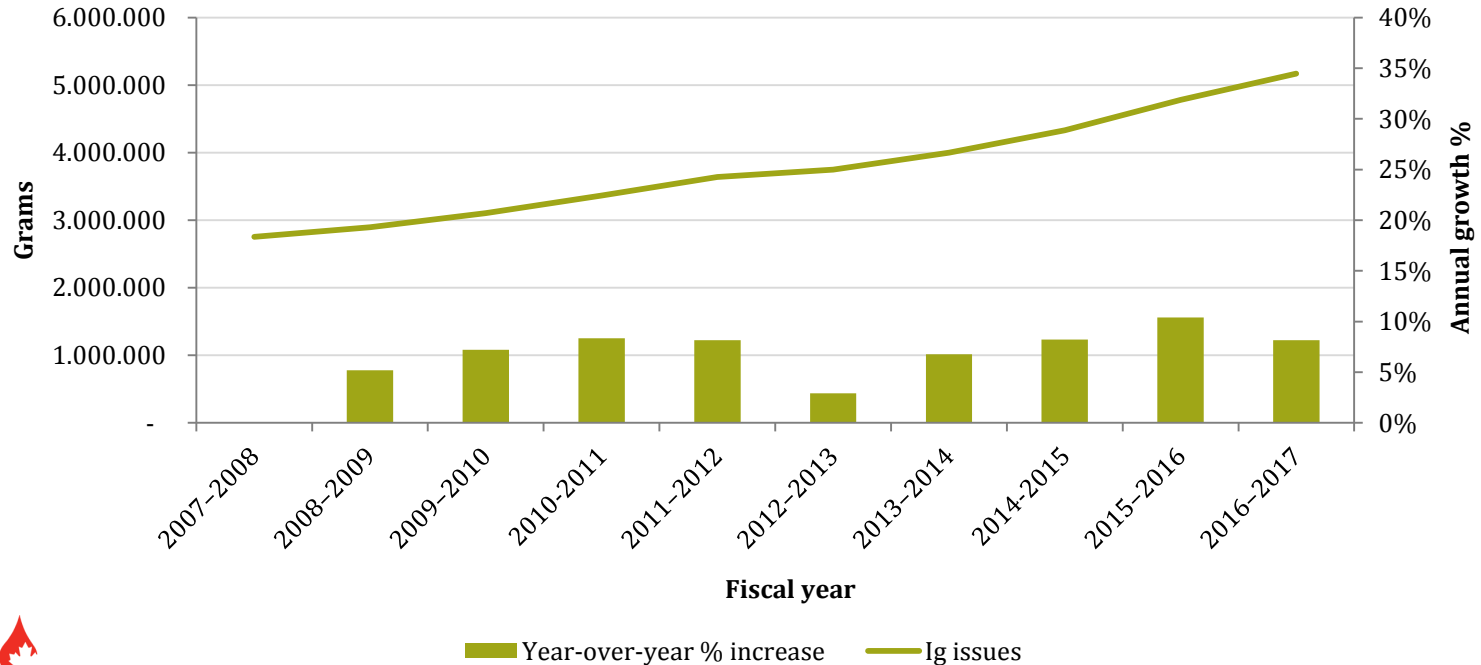
THE CANADIAN POLYVALENT IgG MARKET
FROM 2014 TO 2024
(Metric tons)



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

Grams of Ig used for priority indications

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

*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.

Grams of Ig used for priority indications

Indication	Grams		
	U.K.	Australia	Canada
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%

Ig utilization in Canada

Utilization has continued to increase, even in provinces with well established “gatekeeping” models.

- Many provincial blood offices have initiatives designed to decrease inappropriate or unapproved Ig utilization
- Restricting use to appropriate indications may not lower demand for Ig products in the future
- To reach the desired level of sufficiency, Canada will have to increase collections to meet growing Ig demand

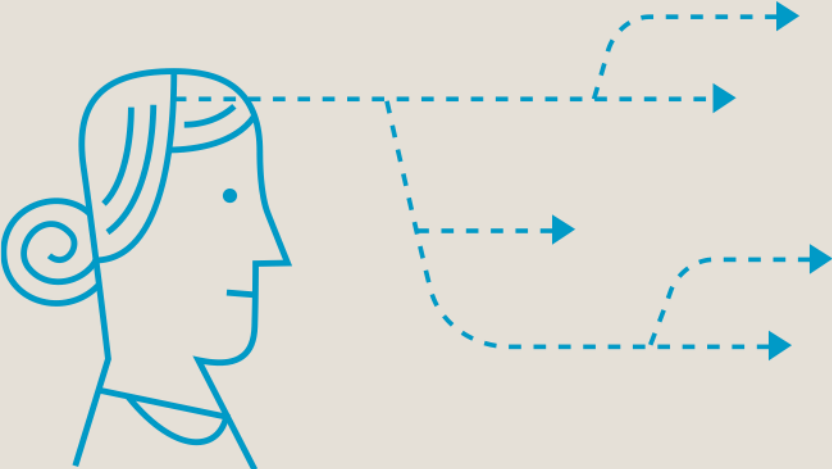
Ensuring security of the Canadian plasma supply for Ig

Maintaining the status quo places Canadian patients at risk.

- Submitted business plan to mitigate growing risk to supply of plasma needed to manufacture Ig for Canadian patients to governments in January 2017
 - 50% sufficiency target proposed for Canada
 - Given known risks and potential impacts Ig supply constraints would have on patients, it is important to act swiftly
 - Australia and several European countries are similarly making plans to significantly increase plasma collection via public system (Denmark, Belgium, Netherlands, France, Spain and Italy)



Stakeholder dynamics in Canada



An organization created out of crisis

Canadian Blood Services was founded based on recommendations from the Krever Report on the tainted blood scandal.

- Accountable to governments and the Canadian public for meeting 100 per cent of patient need for Ig
- Collect the volumes of blood and blood products, including plasma, needed for Canadian patients
- Determine and monitor plasma sufficiency for the country on behalf of governments

Stakeholder influence

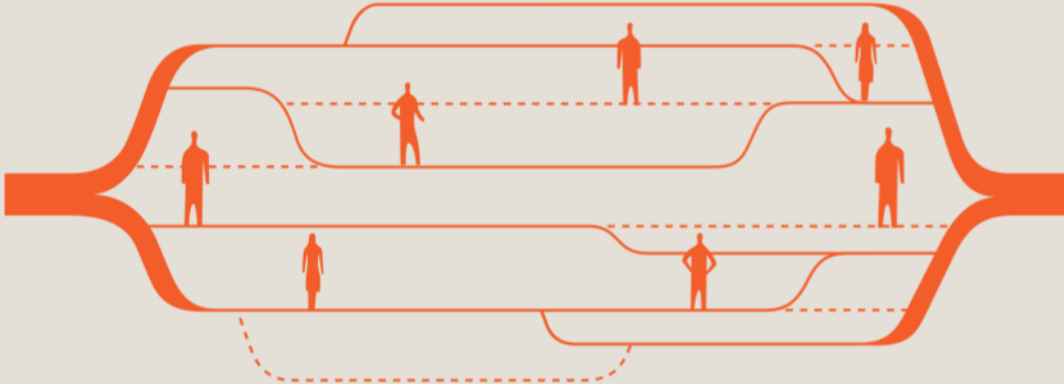
As the stewards of Canada's blood system, we work with all levels of government, patient organizations, suppliers, global experts, our counterparts in other countries and other stakeholders.

- Patients first
- High level of public interest and engagement
- Account for stakeholder concerns in our decision-making

Stakeholder input and concerns

- Primary concern for patient groups is ensuring a secure supply of safe products for patients who rely on them
- Concern about allowing for-profit operators to collect plasma and dilution of public control over blood/plasma
- Divergent perspectives regarding the appropriate sufficiency target
- Preference for non-remunerated model but openness to providing incentives; some were also open to Canadian Blood Services paying donors

Geopolitical landscape



Common attributes of countries with successful national plasma collection

- Success factors include:
 - Dedicated centres for plasma collection to optimize operating efficiency
 - Well-functioning, competent regulatory bodies
 - Focus on donor and product safety in conformance with Good Manufacturing Practices
 - No wastage of recovered plasma from whole blood donations
 - Consideration of plasma as a global resource (in Canada, aligns with recommendations in Krever report)

Differing views on donor remuneration

Canada's provincial governments have taken different positions on payment for plasma donations.

- 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, for-profit plasma collector planning to set up collection sites
- Alberta and British Columbia passed legislation similar to Ontario law in 2017 and 2018, respectively
- New Brunswick, Manitoba and Saskatchewan currently permit payment



Differing views on donor remuneration

Canadian Blood Services is necessarily exempt from the legislation enacted in Ontario, Alberta and British Columbia.

- Canadian Blood Services intends to increase plasma collection through our voluntary, non-remunerated model
- Issue of payment is publicly debated in Canada

Donor remuneration is a topic of international discussion.

- In the Netherlands, Sanquin is reportedly considering offering a modest compensation to Dutch blood and plasma donors to cover donation-related expenses*.

Crowding out (“spiazzare”)

When for-profit, paid plasma systems expand rapidly, they can impact the ability of not-for-profit blood industry to meet its blood collection targets.

- Example in United States
- Early evidence of impacts in Canada
- Potential emergence of large-scale, commercial for-profit collectors in Canada is a concern
- As the publicly owned and accountable entity, we are able to make informed and holistic decisions about where, when and how to collect plasma to ensure the supply needs of Canadian patients are met into the future



Leveraging best practices from the private sector

We are interested in drawing on **(ATTINGERE)** the significant plasma collection expertise of the commercial plasma industry to ensure our efforts succeed in a cost-efficient manner. However...

- Commercial plasma collectors acting on their own will not alleviate concerns about Canadian security of supply
- Commercial for-profit business models do not support national sufficiency planning; only the public blood authority does this on behalf of the country and Canadian patients



Federal government expert panel report

- Federal Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada released report in May 2018
- **Key findings:**
 - **Demand for plasma is projected to continue to increase**
 - Security of plasma supply for Ig is a **critical public health-care issue** for Canada
 - Canadian Blood Services' **plan to collect more plasma is an appropriate response**

Federal government expert panel report

- Report also notes:
 - Better Ig utilization management in Canada is needed to address demand, recognizing utilization alone will not solve the sufficiency problem
 - Canada’s blood system must also collect more plasma
 - “Crowding out” requires ongoing oversight, monitoring and vigilance

Conclusion



Canadian Blood Services
it's in you to give

The recommendation for Canada:
Long-term security of supply is
achieved through increased
plasma collection within the
national, not-for-profit system.

Conclusion

A public sector solution to security of supply

As the publicly owned and funded entity, we are accountable for ensuring an adequate supply for Canadian patients.

- Commercial collectors outside of the national blood system have no responsibility for, or accountability to, the national blood system
 - May not recognize the impact their activities could have on whole blood collections from unpaid donors
 - Not bound to keep plasma collected from paid Canadian donors in Canada
- Public sector approach allows us to mitigate impacts of private sector; pragmatic solution





Canadian Blood Services
it's in you to give