

Navigating complexity: Ensuring security of supply of PDMPs in the Canadian context

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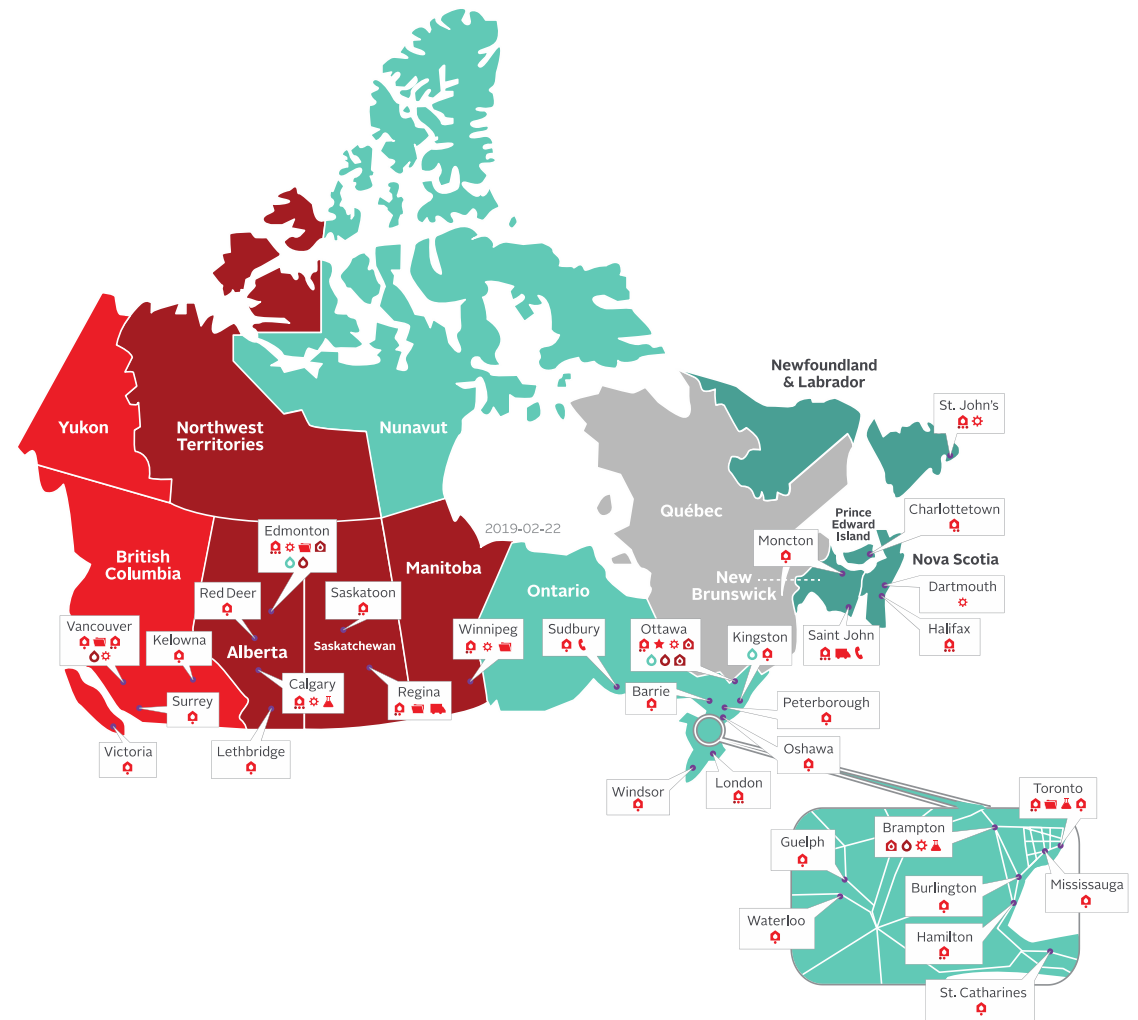
**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

Plasma risk in the Canadian context

Canada in context

- Population = 37 million (29M excl. Quebec)
- Canadian Blood Services:
 - Responsible for national, integrated services for Canadian hospitals and patients (excluding Quebec)
 - Product lines include blood, plasma, stem cells, organs & tissues
 - “Plasma” includes:
 - Collection of raw material
 - Contract (toll) manufacturing of all plasma derivatives
 - Acquisition of plasma protein (and recombinant) therapies from commercial market



Legend

- | | | |
|--|-------------------------------------|-------------------------|
| Whole Blood, Platelets and Plasma Collection | Testing | Diagnostic Services |
| Whole Blood and Platelets Collection | Distribution Centre | Stem Cell Collection |
| Whole Blood and Plasma Collection | Cord Blood Collection | National Contact Centre |
| Whole Blood Collection | Cord Blood Manufacturing | Head Office |
| Production | Plasma Protein Product Distribution | |

Our strategic plan 2019–2024

Five key focus areas



Meet changing patient needs by providing lifesaving products and services.



Build and deepen relationships with the donors of the future.



Ensure a secure supply of Canadian plasma for immune globulin.



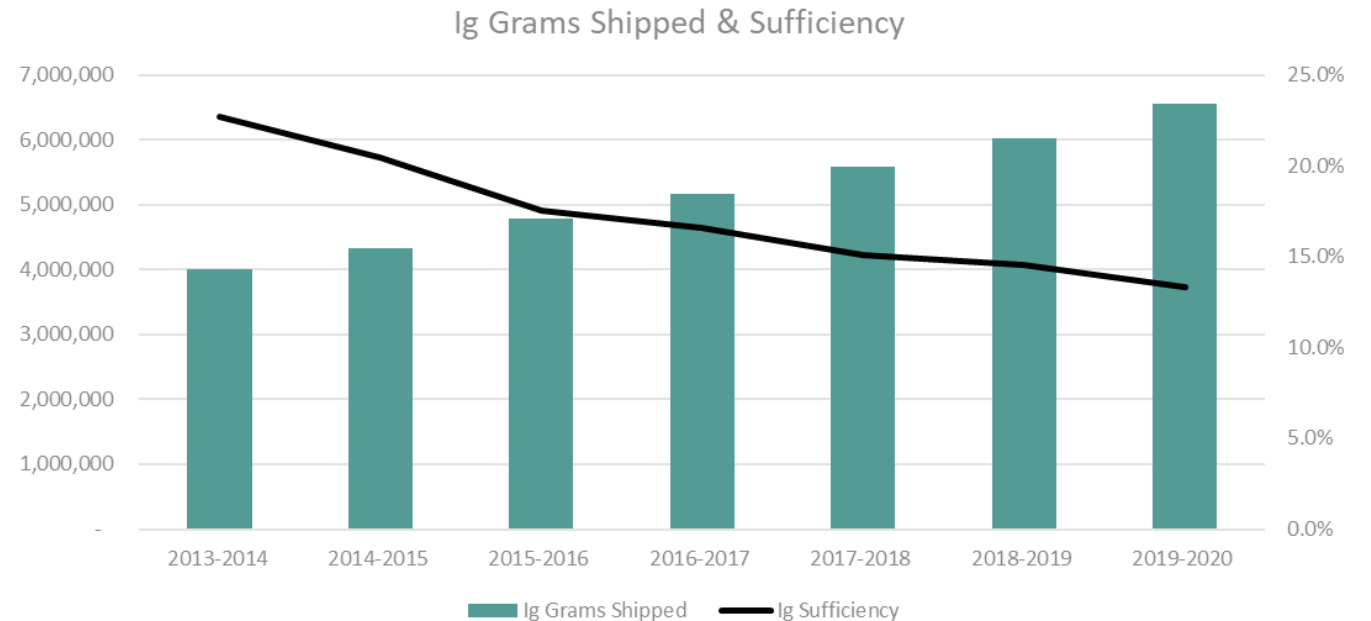
Create an engaging and empowering employee experience.



Achieve organizational excellence.

Canada is one of the highest users of Ig *per capita*

- In the last 10 years, Canada's rate of usage for immune globulins (Ig) has increased **111 per cent**
- Ig consumption rate approx. **219 g per 1,000 population**
- Wide geographic variation (New Brunswick **191 g per 1,000 population** to Alberta **297 g per 1,000 population**)
- Canadian plasma sufficiency rate for Ig is now at **13.5 per cent**



Sufficiency level has changed over time



- Pursuing a sufficiency level of 100 per cent or self-sufficiency, is not recommended as it transfers all of the supply risk onto the Canadian plasma collection system
- For Canada, risk modelling suggests **50 per cent target** balances the supply risk and ensures sufficient Ig to meet all needs of critical patient groups (for which no alternative exists)
- Purchasing more than 50 per cent of Ig product from suppliers or rationing Ig to exclude the treatment of other patient populations are not viable solutions

Immune globulin utilization

- Within Canada, there are provincial initiatives in place with the common goal of influencing and optimizing the utilization of Ig products — the overall impact of these provincial initiatives is variable
- Increases in utilization continues to occur in most provinces, despite Ig utilization programs being in place
- The growth of Ig utilization is largely occurring for approved indications - the proportion of inappropriate use is thought to be low (4% – 11%)
- Using less is not the only answer - we need to collect more to make more
- A deliberate, proactive build-up of capacity to collect plasma for fractionation, implemented in a sustainable manner is recommended

Our strategic plan



Ensure a secure supply of Canadian plasma for immune globulin.

- Significant expansion of source plasma collections under auspices of Canadian Blood Services
- Target approx. 50% sufficiency of Ig needs for Canada
- **Collect source plasma at market proximate price, from non-remunerated donors**
- Mitigate risks by diversification of raw material base, fractionation capacity, finished goods suppliers and other related factors:
 - **Supply AND cost are risk factors**
 - Lead time to reverse this risk and increase available plasma for the manufacture of ig is significant

Securing Canada's plasma supply for PDMPs

Increasing source plasma in Canada



Increase
collections in
our existing
network

Dedicated
stand-alone
source
plasma
collections

Balance our
portfolio by
purchasing
commercial
product

A global response with local implications

- Canadian Blood Services is not alone in responding to the global supply risk for PDMPs
- Value in collaborating and sharing best practices among voluntary blood sector organizations
- Plans to increase source plasma collections (models for recruitment, collections, supply chain operations, sufficiency targets etc.)
- Also leveraging expertise from large-scale commercial (remunerated) plasma sector, especially for applicable models of operational efficiency



Increase collections in our existing network - large volume source plasma

- All source plasma collections in two existing blood centres (London and Calgary) now directed for fractionation
- Increased per collection volume from 500ml up to 880ml — potential for up to 37 percent more plasma per donation
- Annual target for these existing sites 14,000 litres
- Assessing feasibility of expanding source plasma collection in other existing blood collection sites
- A small contribution, but supports the strategy and the target



First LVSP donor

Stand-alone source plasma (proof-of-concept)

- Dedicated source plasma collections program:
 - Initially launching three plasma-only donation centres
 - Sudbury, ON
 - Lethbridge, AB
 - Kelowna, BC
 - 12 or 16 bed models at launch; repurpose prior WB markets
 - Each site will collect 20,000L when operating at capacity
 - Develop and grow a robust non-remunerated plasma donor recruitment program
 - Price per litre set at a target that is proximate to global price for source plasma
 - Highly efficient processes
 - Lean staffing model with multi-skilled workers
 - Longer hours of operation
 - Dedicated recruiters with strong links to the community



A strategic choice to transform whole blood markets

- When looking at the optimal conditions for success with the proof of concept sites, we considered an approach that would have the least amount of impact on our supply chain
 - Size and demographics of market
 - Donor base potential and psychographic data
 - Distinct media markets and proximity to paid plasma
 - Declining whole blood markets with strong donor potential
 - Already an established presence in the community
 - Target converting at least 30 per cent of active blood donors

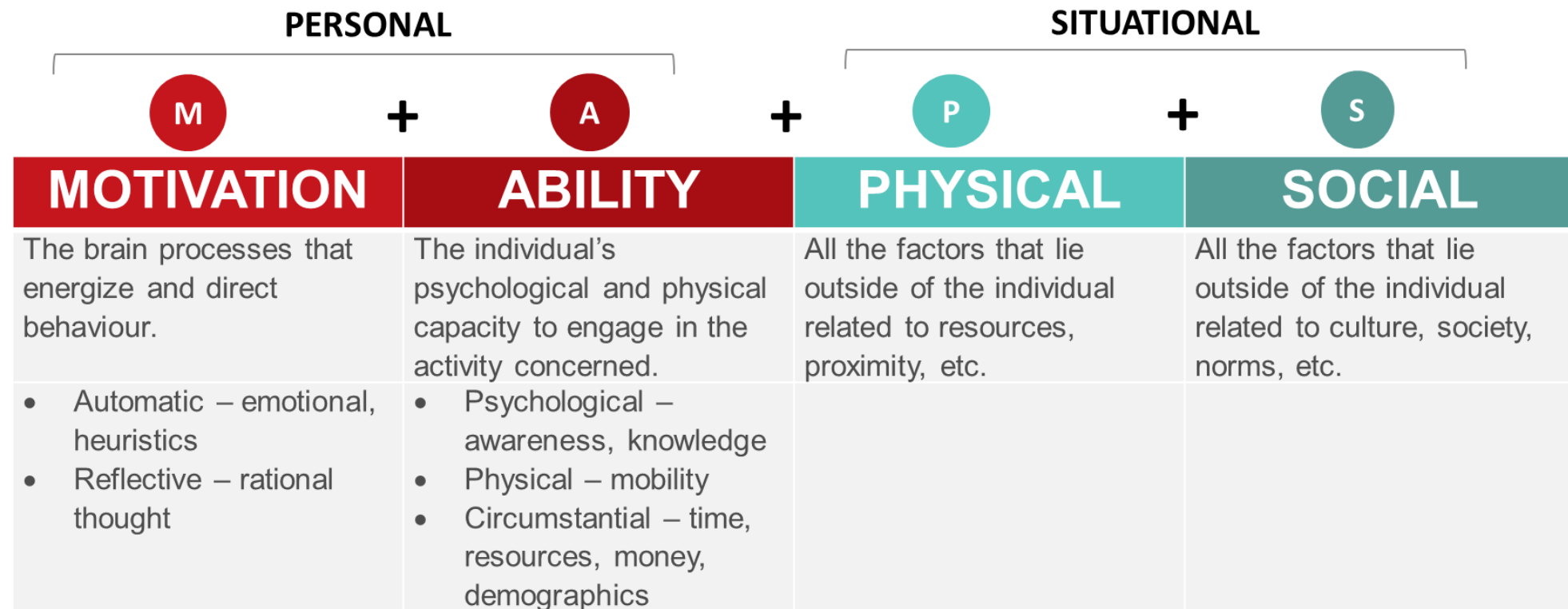


Plasma will succeed and not at the expense of whole blood

How will we attract enough donors?

MAPS Framework Overview

Sources of Behaviour (IPSOS Maps Model)



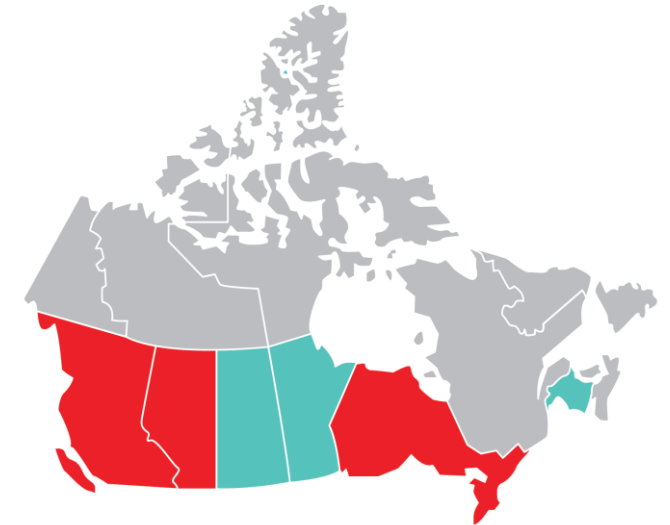
Stakeholder dynamics in geopolitical landscape in Canada

Stakeholder input and concern

- High level of public and political interest and engagement, with diverse perspectives
 - Rooted in legacy of tainted blood era and Krever Inquiry; distortion of fact basis with respect to current risks
- Primary concern for patient groups is ensuring a secure supply of safe products for patients who rely on them
- Divergent perspectives regarding the appropriate sufficiency target
- Preference for non-remunerated model but openness to providing incentives; some stakeholders also open to Canadian Blood Services paying donors
- Concern about allowing for-profit operators to collect plasma and dilution of public control over blood/plasma

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
 - Alberta passed legislation similar to Ontario law in 2017, followed by British Columbia
 - Canadian Blood Services is necessarily exempt from the legislation enacted in Ontario and Alberta
 - For-profit collection present in three Canadian provinces: New Brunswick, Saskatchewan and Manitoba



"Crowding out" in the Canadian context

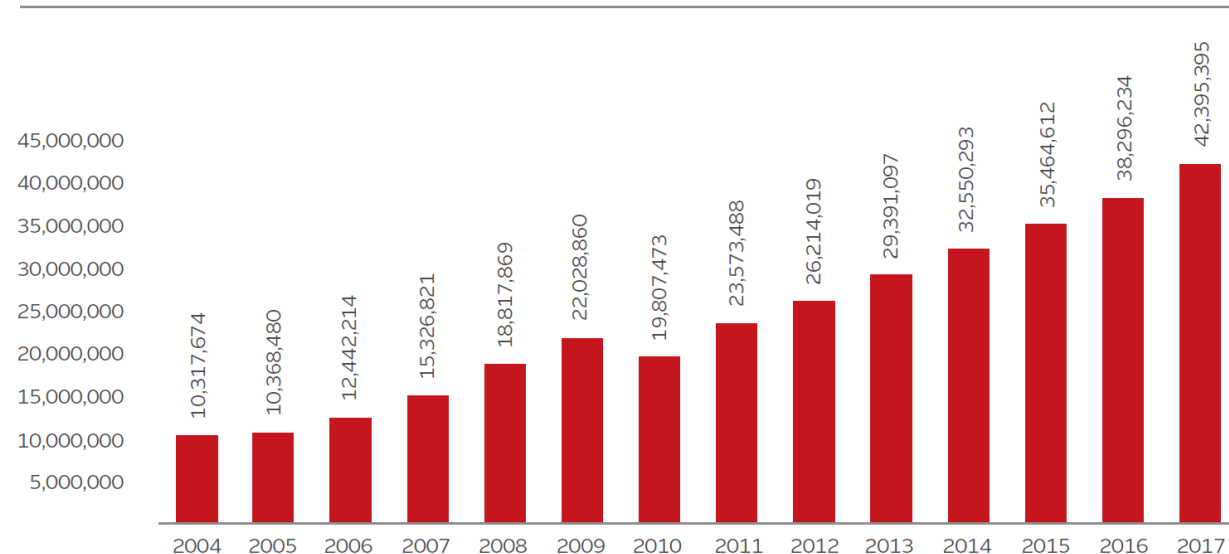
Canadian Blood Services:

- Publicly owned and mandated to ensure security of supply of blood and all PDMPS
- Makes informed and holistic decisions about where, when and how to collect plasma to ensure the supply needs of Canadian patients are met
- Commercial, for-profit plasma collectors acting on their own:
 - Not necessarily focused on domestic security of supply
 - May pose competitive threat to donor acquisition in certain markets
- Single, long-standing entity (Cangene/Prometic), with niche product portfolio, has co-existed in Winnipeg for decades with no impact
- More recent emergence of paid plasma operations:
 - Has resulted in some evidence of market and brand confusion, transient dips in blood collection (in 17-24 age cohort), but no sustained impact
- Canadian Blood Services commissioned a study with ProGuide Management Resources:
 - "Potential Encroachment of Source Plasma Operators into the Blood Industry in the United States and Europe"

Impact of plasma expansion

- To meet demand for products, plasma collection continues to expand in the US:
 - 500 paid plasma collection sites in 2015, more than 800 in 2019
 - Total source plasma collections in the US exceeded 42 million litres in 2017

US source plasma collections

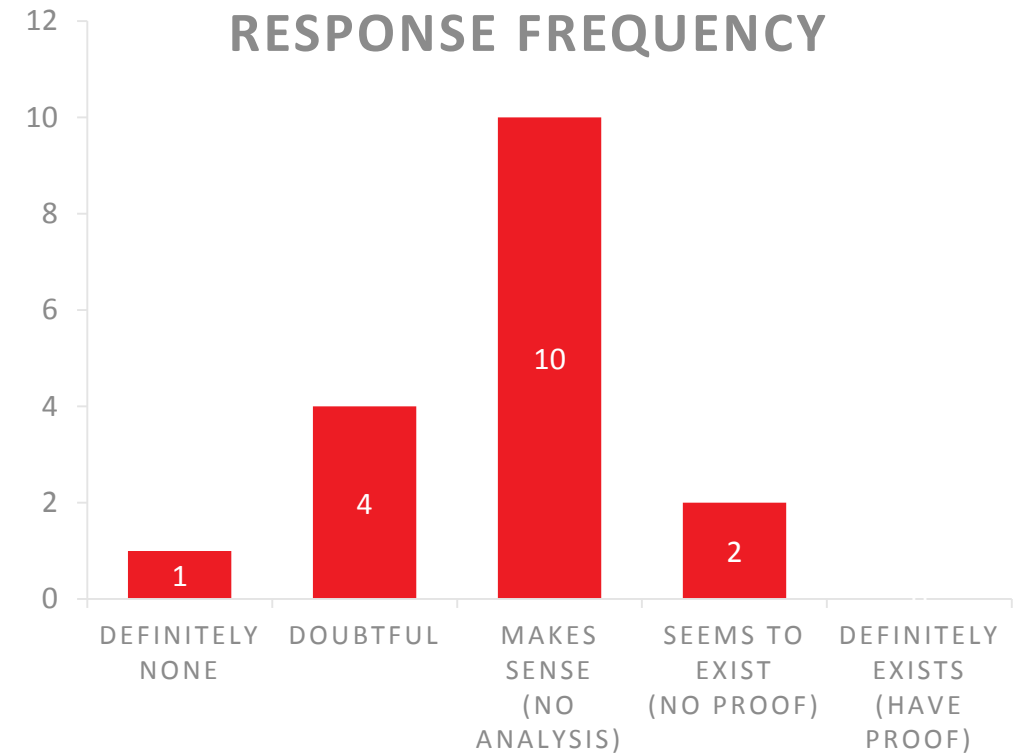


"Crowding out" of the voluntary blood sector by rapid expansion of paid, commercial plasma collections

- "Encroachment" better describes the phenomenon
- Many executives in the U.S. blood industry have opined that the fast-paced growth in paid plasma collections have encroached upon their organizations' ability to collect sufficient blood products
- Data and evidence to support this has been lacking
- PPTA and commercial plasma collectors have denied any impact
 - Recent study even suggested a "crowding in" impact
- Gathering the evidence in an objective, unbiased way is challenging, and many entities are unwilling to share necessary data
- We sought to quantify the impact using third party expertise, and all publicly available and openly reported data

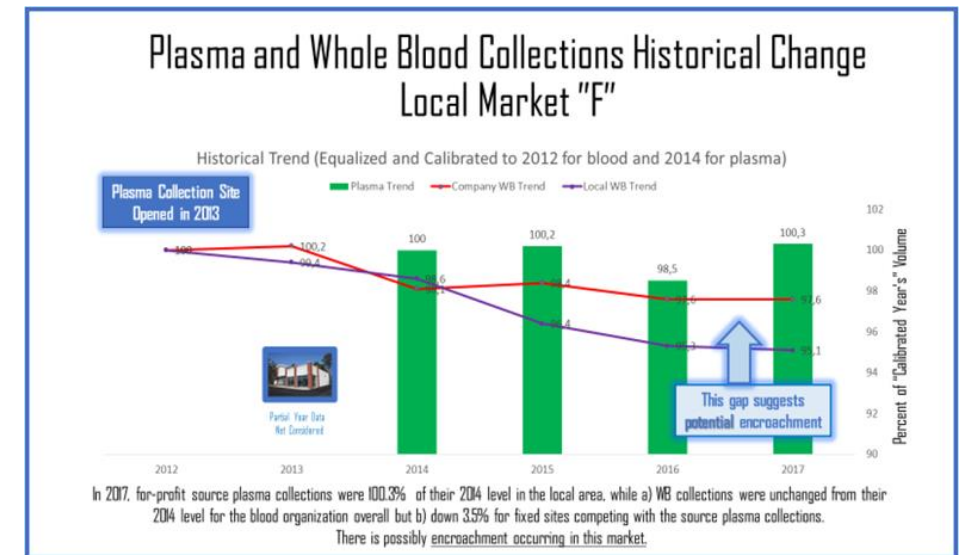
"Crowding out" of the voluntary blood sector by rapid expansion of paid, commercial plasma collections

- 20 randomly-selected geographical areas in the U.S. where paid source plasma programs operate alongside traditional blood centers were examined for impacts of encroachment
- Data from seven blood operators (including ARC) as well as BCA, and from 5 commercial plasma collectors (all de-identified for source)
- Data covers 12 states and 20 cities:
 - AustinTX, Bakersfield CA, Billings MT, Bismarck ND, Casselberry FL, Columbus OH, Gainesville FL, Grand Rapids MI, Indianapolis IN, Jacksonville FL, Knoxville TN, Lima OH, Lubbock TX, Memphis TN, Orlando FL, Phoenix AZ, Pittsburgh PA, Santa Fe NM, and Tempe AZ
- General opinion from querying executive leadership of the blood centres – “It seems sensible to conclude that this phenomenon exists but more data is needed.”



Study findings: Evidence of encroachment

- Data failed to display any **clear** evidence that the growth in paid source plasma programs has been a direct detriment to the traditional blood organizations
- In select markets where the fixed sites are underperforming and collections have significantly eroded well beyond the overall decline of their parent blood center, **something(s) must account for this — one possibility being encroachment**
- Other factors could include greater reliance on mobile operations, competitive pressures, financial decisions to shift collections model etc.
- Further study is needed



Study findings: Europe

- Less able to extract operational data and perform any quantitative analysis
- Relied on interviews with key opinion leaders and executives from regional and national blood services in Austria, Germany, Czech Republic and Hungary
- Substantial variation across each country and region
- Notable differences in where and how the blood and plasma sectors operate in each country, and whom they target as donors

Study findings: Europe

- Bottom line: no evidence of VNRBD being tangibly impacted by remunerated source plasma operations
- Some interesting observations:
 - Some blood services have had to significantly increase their expenditure on marketing activities over last few years
 - Cannot link this causally to emergence of plasma collection operations
 - In Hungary, the blood service successfully lobbied the national government to require paid plasma donors to make at least one unpaid whole blood donation per year. Over 30,000 such “certificates” issued in 2018, representing four per cent of total annual blood donations

Summary

- Ability to leverage existing infrastructure, capability, network and systems; also applying lessons and best practices from others
- Doing it responsibly, to mitigate any impacts on the mature voluntary non-remunerated blood donor environment
- Concerns about encroachment by the commercial, for-profit (paid) plasma sector on the voluntary non-remunerated blood donor sector are more than theoretical, even though definitive evidence is lacking
- Both the blood sector and the plasma sector have patient interests at heart
- Neither should seek to harm or otherwise interfere with the other
- Not every region or country will take the same approach to source plasma acquisition
 - Societal, cultural, public health, and geopolitical factors are different and do influence program evolution

Canada needs to substantially increase its source plasma collection capability and capacity with the objective of achieving domestic security of supply for Canadian patients - in our context, this is best done in the publicly accountable, nationally mandated blood system



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