

**MINISTRY OF HEALTH
DECISION BRIEFING NOTE**

Cliff # 1089862

PREPARED FOR: Honourable Adrian Dix, Minister of Health - **FOR DECISION**

TITLE: Canadian Blood Services Business Plan for Plasma Security

PURPOSE: To provide a decision on whether to support the Canadian Blood Services Business Plan: Ensuring Security of the Canadian Plasma Supply for Immune Globulin

BACKGROUND:

On January 20, 2017, Canadian Blood Services (CBS) submitted *Ensuring Security of the Canadian Plasma Supply for Immune Globulin* (the Plan) to Provincial/Territorial (PT) Ministers of Health, Deputy Ministers (DMs) and PT Blood Liaison Committee members (see Appendix A).

The Plan outlines CBS's proposal to increase Canada's plasma sufficiency for immune globulin (Ig) from 17 to 50 percent^{s.13; s.21}. CBS is targeting 50 percent sufficiency to meet the demand for patients requiring Ig for life saving treatment. Sufficiency of 100 percent is not targeted as this would transfer all the risk of supply to the Canadian system.

s.13; s.21

DISCUSSION:

The CBS Corporate Plan 2018-2021, (see Appendices B and C) contains^{s.17; s.21}

s.17; s.21

Significant assumptions are made in the Plan regarding events that could affect future global supply of plasma and demand for Ig. Health Canada recently announced the formation of an expert panel to gather evidence regarding the plasma sufficiency and collection models. The Chair of the panel is Dr. Penny Ballem, Clinical Professor at the University of British Columbia's Faculty of Medicine and former BC Deputy Minister of Health.

Dr. Francine Décary, a haematology research scientist and blood system executive and expert, will also participate on the panel. Additional panel members may be named. The final report from the expert panel is expected by March 31, 2018.

Canadian Blood Services has had ongoing blood inventory challenges in 2016 and 2017 due to a combination of factors including extreme weather, updated hemoglobin guidelines and increased demand. Diverting whole blood donors to plasma donation could further impact these challenges. s.13; s.21

s.13; s.21

OPTIONS:

Option 1: Await the findings of the expert panel in 2018, before considering funding for proof of concept plasma collection sites in 2019/20.

Pros: s.13

Cons:

Option 2: s.13

Pros:

Cons:

FINANCIAL IMPLICATIONS:

s.17; s.21

Additional capital costs will be required in subsequent years to maintain 50 percent sufficiency as Ig demand continues to grow.

s.17; s.21

RECOMMENDATION: Option 1: Await the findings of the expert panel in 2018, before considering funding for proof of concept plasma collection sites in 2019/20.



February 23, 2018

Approved/Not Approved

Date Signed

On behalf of : Adrian Dix

Minister of Health

Appendix A: Ensuring Security of the Canadian Plasma Supply for Immune Globulin

Appendix B: CBS Corporate Plan 2018-2021, Book 1

Appendix C: CBS Corporate Plan 2018-2021, Book 2

Program ADM/Division: Ian Rongve, ADM, Hospital, Diagnostic and Clinical Services Division

Telephone: 250-953-4504

Program Contact (for content): Wendy Vowles, Director, Blood Services, HDCS Division

Drafter: Heather Davidson, Senior Program Analyst, HDCS Division

Date: September 5, 2017

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s.16 ; s.21

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s.13 ; s.16 ; s.21

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s.16 ; s.21

**MINISTRY OF HEALTH
DECISION BRIEFING NOTE**

Cliff # 1124324

PREPARED FOR: Stephen Brown, Deputy Minister of Health - **FOR DECISION**

TITLE: Canadian Blood Services Plasma Collection Sites

PURPOSE: 2019/2020 funding decision for three Canadian Blood Services plasma collection sites

BACKGROUND:

Canada is self-sufficient in the collection of plasma for transfusion but relies, through Canadian Blood Services (CBS), on plasma collected from paid donors in the United States for fractionation of plasma protein products.

The federal Expert Panel on Immune Globulin (Ig) Product Supply and Related Impacts in Canada (the Panel) released a report in May 2018, in which greater plasma self-sufficiency in the collection of plasma for the creation of Ig was encouraged. The Panel has suggested that Canada focus on the ability to provide sufficient plasma to meet the needs of patients who are life dependent on Ig. CBS has identified this targeted level of Ig sufficiency at 50 percent.

Provinces and Territories (PTs) continue to work collectively and individually on utilization management to slow the growth in demand for Ig. British Columbia has one of the most comprehensive programs in Canada, run by the Provincial Blood Coordinating Office; however, demand for Ig continues to climb. Canada's sufficiency level is expected to drop to 13 percent by 2019/20. The sufficiency rate was 15 percent in 2017/18 (Attachment 1) when the Panel examined this issue.

Despite the rate of self-sufficiency for plasma in Canada at that time, the Panel did not consider this to be a national crisis or emergency.

DISCUSSION:

CBS is requesting ^{s.21} (^{s.17} for British Columbia) in 2019/20 to begin establishing three proof-of-concept plasma collection sites (Attachment 1, Appendix A).

s.16; s.17

CBS has been working with a large multi-national pharmaceutical company with industry expertise in source plasma collection. Based on the learnings from this partnership exchange CBS plans to locate the three collection sites in mid-sized markets in British Columbia, Alberta and Ontario. Further details on these locations are expected at the end of December 2018.

If funding is approved, the first site will open in March 2020, with six months between site openings for 'test and learn' assessment and adjustments. With the additional plasma collected through current infrastructure and proof-of-concept sites, Canada's sufficiency is expected to hold steady at around 13 percent, rather than continuing to fall.

Approval of the budget will be decided by a majority vote. Following agreement by PTs and CBS, the budget will be brought to the Deputy Ministers of Health for recommendation for approval by Ministers of Health as Corporate Members of Canadian Blood Services.

OPTIONS:

Option 1: Support funding CBS to begin establishment of three plasma collection sites.

Pros: The decline in Ig sufficiency may cease, reducing Canada's reliance on the United States for plasma for fractionation.

Cons: PTs are committed to ongoing operational costs for these sites.

Option 2: British Columbia does not support this funding request by CBS.

Pros: CBS will continue to work toward incremental increases in plasma collection within the existing budget.

Cons: Canada's level sufficiency will continue to decline as demand for Ig grows.

FINANCIAL IMPLICATIONS:

s.17

RECOMMENDATION:

Option 1: Support funding CBS to begin establishment of three plasma collection sites.



November 27, 2018

Approved/Not Approved
Stephen Brown
Deputy Minister

Date Signed

Attachment 1: Increasing Source Plasma Collections 2018-10-31

Attachment 2: Increasing Source Plasma Collection in Canada 2018-10-10

Program ADM/Division: Ian Rongve, ADM, Provincial Hospitals Laboratory Health Services
Telephone: 778-698-1737 **Program Contact (for content):** Wendy Vowles, Director, Blood Services, HPLHS
Drafter: Wendy Vowles, Director, Blood Services, PHLHS **Date:** updated November 23, 2018

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s.16 ; s.21

**MINISTRY OF HEALTH
DECISION BRIEFING NOTE**

Cliff #1210549

PREPARED FOR: Stephen Brown, Deputy Minister of Health - **FOR DECISION**

TITLE: 2022-23 Request for Additional Plasma Collection Sites

PURPOSE: To get direction on BC's vote regarding Canadian Blood Services' 2022-23 request for an additional three plasma collection sites.

BACKGROUND:

In March 2019, Provinces and Territories (PTs) approved ^{s.16} in the 2019-20 budget to open three proof-of-concept (POC) Plasma Collection Sites (PCS) to be located in Sudbury, ON, Lethbridge, AB and Kelowna, BC. The sites opened between August 2020 and June 2021.

In March 2021 PTs approved ^{s.16} for 2021-22 to establish two additional PCS and to plan for a third, providing all PCS adhered to the Conference of Deputy Ministers approved reporting framework. The sites in Brampton, ON and Ottawa, ON will open in Spring 2022.

In the 2022-23 budget request, CBS is seeking:

- Operational funding for the five previously approved sites (^{s.16} nationally; BC estimated costs ^{s.17} ¹; and,
- Approval to open an additional three PCS.
 - Winnipeg, MB or Abbotsford, BC – Fall 2022 and two more sites - Spring 2023.
 - Start-up costs, estimated at \$ ^{s.16} are expected to be covered by Health Canada. CBS and Health Canada are finalizing the contribution agreement.

BC supports the annual operating budget request for the five previously approved sites.

PTs will vote on the additional three sites during budget negotiations between PTs and CBS (November 23 to 26, 2021).

DISCUSSION:

Although there is no financial impact for PTs in 2022-23 for the three new PCS, PTs will be responsible for the ongoing operational costs. CBS estimates that the annual operating costs for will be ^{s.16} per site (^{s.16} total) when at full collection capacity².

The goal of the plasma collection program is to increase Canada's domestic supply of plasma for further manufacture into immunoglobulin. As of September 30, 2021, the plasma sufficiency rate is 15 percent, which falls well below the target of 50 percent.

In August 2020, BC supported the approval of two additional PCS (in 2021-22); however, approval for additional sites would be contingent upon the five PCS demonstrating success, as defined in the POC reporting framework.³ The first Annual Report for Proof-of-Concept

¹ Source: 2022-25 Corporate Plan, p81.

² Source: 2021-24 Corporate Plan, p54.

³ Source: BC DM email to DM Spidel regarding 2021-22 Request for Plasma Collection

Collection Sites received October 29, 2021 stated that ^{s.21}

s.21

s.21

See Appendix A.

OPTIONS:

Decisions regarding funding for additional PCS are made by PT consensus, therefore, regardless of BC's vote the project could be approved or denied.

1. BC votes to approve three additional sites in 2022-23, conditional upon start-up funds being provided by Health Canada.

Pros: Increase the domestic plasma supply; No financial impact to BC in 2022-23.

Cons: Ongoing operational costs estimated ^{s.16} per year (BC ^{s.17}) beginning in 2023-24.

2. BC votes to approve three additional sites in 2022-23, without confirmation of Health Canada funding.

Pros: Increase the domestic plasma supply.

Cons: Ongoing operational costs estimated ^{s.16} per year (BC ^{s.17}) beginning in 2023-24 and BC's share of start-up cost of the ^{s.16} (BC ^{s.17}) ^{s.17} start-up costs in 2022-23.

3. BC votes against approval of three additional sites in 2022-23.

Pros: Allow more time to determine if POC will be a viable investment.

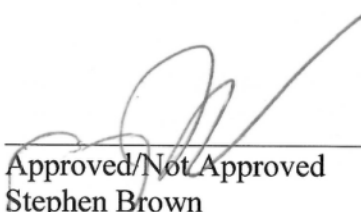
Cons: Delays the expansion of plasma collection within the public blood system and may negatively impact plasma supply.

FINANCIAL IMPLICATIONS:

BC's share of the ongoing annual operating costs is estimated at ^{s.17} . One-time start-up costs of ^{s.16} is expected to be funded by Health Canada.

RECOMMENDATION:

Option 1 - BC votes to approve three additional sites in 2022-23, conditional upon start-up funds being provided by Health Canada.


Approved/Not Approved
Stephen Brown
Deputy Minister

NOV 23 2021
Date Signed

Program ADM/Division: Mitch Moneo, PLSBSD

Telephone: 250 952-1464

Program Contact (for content): Katherine Leong, A/Director Blood Services

Drafter: Katie MacNeill, A/Senior Program Advisor, Blood Services

Date: November 17, 2021

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s.16 ; s.21

BRIEFING NOTE - SOURCES

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s.16 ; s.21

EMAIL RESPONSE

1181571

Mr. Mark Spidel
Deputy Minister

s.16

Dear Mr. Spidel:

Thank you for your email of November 13, 2020, to Mr. Stephen Brown, Deputy Minister, regarding the Canadian Blood Services (CBS) budget for 2021-22. As the Assistant Deputy Minister for the blood services portfolio, I am happy to respond on his behalf.

s.16; s.17

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical, Laboratory and Blood Services Division
BC Ministry of Health

pc: Brian Berthelsen, Senior Policy Lead, PEI Department of Health and Wellness
Katherine Leong, A/Director, Blood Services, BC Ministry of Health

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s.13 ; s.16 ; s.17 ; s.21

From: Minister, HLTH HLTH:EX
To: "brian.postl@umanitoba.ca"
Cc: "Graham.Sher@blood.ca"
Subject: 1239055 - BC Minister of Health Correspondence
Date: September 2, 2022 2:35:33 PM
Attachments: 1230955 Min to Dr Postl re Plasma Collection.pdf

Good afternoon,

Please find attached correspondence from the Honourable Adrian Dix, Minister of Health in British Columbia, regarding Canada's plasma sufficiency.

Thank you,
Corporate Operations Unit
Ministry of Health

Gratefully Acknowledging the Traditional Homelands of the Lekwungen Peoples of the Songhees & Esquimalt Nations

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September 2, 2022

1239055

Via email: brian.postl@umanitoba.ca

Dr. Brian Postl
Chair, Board of Directors
Canadian Blood Services
1800 Alta Vista Dr
Ottawa ON K1G 4J5

Dear Dr. Postl:

Canadian Blood Services (CBS) is a very important partner in Canada's public health system. As the owner and operator of the public blood system, CBS contributes significantly to life-saving medical treatments by ensuring a safe and sufficient supply of blood and blood products.

Immunoglobulins (Ig) are a life-saving treatment for over 50 percent of the patients who rely on this product. In recent years, the global supply of plasma to manufacture into Ig has been disrupted and constrained, highlighting the importance of a domestic supply of plasma. Therefore, increasing plasma sufficiency is a critical goal to ensure Canadian patients have security of supply.

I understand that a contract has been signed to establish a partnership between Grifols and CBS, which will significantly increase Canada's plasma sufficiency. Under this contract, Grifols will be collecting plasma using a donor remunerated model and will fractionate the plasma into Ig before returning the finished product to CBS.

As you know, in 2018 British Columbia passed the *Voluntary Blood Donations Act (The Act)* that prohibits organizations from paying donors for blood and plasma donations. *The Act* was brought into force to: protect the public blood system from encroachment by the private sector; ensure that plasma collected from British Columbians was used to treat patients in Canada; and, to prevent private entities from exploiting an essential resource and the individuals who generously donate blood.

s.13; s.16

...2

- 2 -

I understand that the partnership with Grifols is one component of CBS' strategy to increase plasma sufficiency. I look forward to further discussions about additional actions to increase plasma sufficiency.

Sincerely,

A handwritten signature in black ink, appearing to read 'Adrian Dix', with a stylized flourish at the end.

Adrian Dix
Minister

pc: Stephen Brown, Deputy Minister of Health
Dr. Graham Sher, Chief Executive Officer, Canadian Blood Services

September 7, 2022

Honourable Adrian Dix
Minister of Health
PO Box 9050 Stn Prov Govt
VICTORIA BC V8W 9E2
Via email

Dear Minister Dix:

Thank you for your letter of September 2, 2022.^{s.16}

s.16

s.16

I appreciate this opportunity to have a dialogue with you on a matter of critical importance to the blood system in Canada.

As you note, in response to an ongoing global shortage of immunoglobulins and risks to cross-border supply chains made worse by the pandemic, Canadian Blood Services is taking action to ensure patients in Canada continue to have long-term access to these lifesaving therapies. This action follows a robust risk analysis via an internationally recognized framework used by blood operators around the world to enable complex evidence-based decision-making.

I understand an overview of this risk analysis was shared with governments earlier this summer; it is guiding the organization's next steps for managing the escalating risks to Canada's supply of plasma for immunoglobulin, quickly and responsibly.

As a reminder, the analysis generated five key recommendations:

1. Undertake additional risk-mitigation measures with urgency;
2. Pursue a targeted range of approximately 50–60 per cent domestic plasma sufficiency to meet patients' most critical needs in Canada — conditions for which no other treatment options exist;
3. Leverage both not-for-profit and commercial sectors, recognizing the reality that commercial plasma is expanding in Canada;
4. Continue work with the National Emergency Blood Management Committee, a pan-Canadian expert advisory body, to address short-term product shortages;
5. Maintain active monitoring of supply and demand for immunoglobulins.

To address recommendation three, Canadian Blood Services has, as mentioned, entered into agreement with Grifols, a global healthcare company and leader in producing plasma medicines, which has manufactured medications at its facilities in the United States from plasma collected in Canada for more than 30 years. With this agreement, which is indeed one part of Canadian Blood Services' overall strategy, Canada will reach a minimum target of 50 per cent sufficiency in the shortest time possible, with Canadian Blood Services increasing and maximizing its plasma collections to achieve approximately 25 per cent as planned, and Grifols' plasma collections in Canada, via their existing donor-remunerated model, delivering the remainder. All of this plasma will then be used by Grifols to manufacture immunoglobulins in Canada, ^{s.13} when the Grifols plant in Quebec is fully operational, exclusively for patients in Canada.

It is important to note that, even with this agreement, Canadian Blood Services will continue to grow capacity to collect more plasma. British Columbia and Ontario are extremely important in this regard. The voluntary blood donations acts in these jurisdictions provide important protections and exemptions for the national blood system. In addition to the eight plasma centres opened or opening soon, including centres in Kelowna and Abbotsford, another three centres will follow in 2024, ^{s.13}

^{s.13} . To your point, and with ongoing government support, there is also potential for future growth of Canadian Blood Services' plasma collections beyond these eleven centres, depending on the country's sufficiency needs.

With specific respect to your comments about the commercial plasma sector in general, you will be acutely aware that for-profit plasma collection has been expanding in Canada for some years now. Canadian Blood Services has consistently maintained that the national system could coexist alongside a few small commercial operations, but that the expansion of large-scale commercial collectors without adequate protections in place posed great risk. Voluntary blood donations acts in Ontario and B.C. have been critical risk mitigators in this regard.

Canadian Blood Services also recognizes governments continue to hold a range of views about commercial plasma collection in the country. Alberta's enactment and subsequent repeal of its voluntary blood donations act is an example of this and offers a view of the environment Canadian Blood Services has been facing over the past number of years on this issue. All governments agree, however, that Canada must increase plasma collection and immunoglobulin sufficiency with some urgency.

Canadian Blood Services' agreement provides a contractual solution to this challenge by ensuring necessary domestic security of supply, with both Canadian Blood Services and Grifols collecting more plasma on behalf of Canadians and manufacturing that plasma on Canadian soil. It also provides essential protections from negative impacts of large commercial industry on national blood system operations,^{s.13; s.16}

s.13; s.16

In brief, this agreement will:

- Provide essential protections for the national blood system, including controls to prevent negative impacts on Canadian Blood Services' current and future network of blood and plasma donor centres.
- Ensure plasma donated in Canada is used to make medications in Canada exclusively for patients in Canada. These controls prevent domestically collected plasma from being sold or shipped offshore.
- Enable Canada's first end-to-end supply chain to meet patients' critical needs for immunoglobulins. Many of these patients have no other treatment option available.

You will also know the safety of products based on the source of plasma donations has never been the concern. For decades, these plasma products have been recognized as extremely safe by regulators, pharmaceutical manufacturers, blood system operators and, most relevantly, the patients and clinicians who use them. Health Canada is responsible for regulatory oversight of the safety of plasma, whether used for transfusion or in the production of drugs. All donor centres in Canada, including Canadian Blood Services' blood and plasma donor centres, and the already existing plasma donor centres operated by the commercial sector in Canada, are authorized and licensed by Health Canada, and must meet strict safety requirements under the *Food and Drugs Act*.

s.13; s.16

s.13; s.16

. To be clear, under this transaction, plasma collected from British Columbians would be used to treat patients in Canada.

I do hope this provides additional and helpful context. We agree that plasma is an essential resource,^{s.13}

s.13

the Grifols' agreement achieves the urgent action and recommended balance of benefits and risks articulated through the risk analysis, the necessary controls to mitigate national blood system encroachment risks, and the delivery of a critical domestic end-to-end immunoglobulin supply

chain for the country, under public sector control and in accordance with the values you have articulated in your letter.

As always, Dr. Sher and I would be more than pleased to meet with you to discuss in more detail at your convenience. Please do not hesitate to contact me again with any further questions or comments. I look forward to continuing to work closely with you and other corporate members of Canadian Blood Services as we respond to significant matters affecting the blood system in Canada.

Sincerely,



Dr. Brian Postl
Board Chair

cc Deputy Minister Brown
Dr. Graham D. Sher, CEO