



Health Canada and the Public  
Health Agency of Canada

Santé Canada et l'Agence  
de la santé publique du Canada

Canada

# **Evaluation of Health Canada's Blood Research and Development Program 2017-18 to 2021-22**

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Prepared by the Office of Audit and Evaluation  
Health Canada and the Public Health Agency of Canada

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## List of Acronyms

BR&D	Blood Research and Development Program
CBS	Canadian Blood Services
G&Cs	Grants and contributions
MOU	Memorandum of Understanding
O&M	Operations and Maintenance
R&D	Research and Development

## Executive summary

This report presents the findings of the evaluation of the Blood Research and Development Program (BR&D) for the period from 2017-18 to 2021-22. The purpose of the evaluation was to examine the impact of activities of the Canadian Blood Services funded by Health Canada under the BR&D Program in supporting the safety of Canada's blood supply system.

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### Program context

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Blood safety was recognized as a major issue in Canada following the contamination of the Canadian blood supply with the Human Immunodeficiency Virus (HIV) and the Hepatitis C virus in the late 1970s throughout the 1980s. In the final report of the Commission of Inquiry into the Blood System in Canada (also called the Krever Inquiry) issued in November 1997, Justice Krever stated that the national blood service should have the facilities and the competence to conduct in-house research and development, as well as to conduct collaborative work between the national blood service and other organizations.

In late 1997, the federal government and the provinces and territories signed a Memorandum of Understanding (MOU) to create the interim National Blood Authority. This MOU also committed \$5 million ongoing per year in support of blood research and development activities. When Canadian Blood Services (CBS) was created in September 1998, it inherited the mandate for coordinating a national research and development program. In Quebec, Héma-Québec was also created in 1998 to supply blood and other biological products of human origin to hospitals in that province. The \$5M ongoing funding has been unchanged in the last 22 years, beyond the blood deferral research related to men who have sex with men (MSM), which totalled an additional \$5.4 million over fiscal years 2016-17 to 2021-22.

Through Health Canada's (HC) Organs, Tissues and Blood Program, within the Strategic Policy Branch, the Government of Canada supports research that contributes to a safe and effective supply of blood and blood products for Canadians. Specifically, HC funds CBS in support of the BR&D Program for basic, applied, and clinical research on blood safety and effectiveness. BR&D activities centre on the following:

- Funding priority research and development programs and projects;
- Engaging in knowledge mobilization (translation and exchange) from creator to user;
- Training highly qualified personnel and building a transfusion science and medicine community of experts; and
- Facilitating collaborative working relationships.

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### Key findings

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The Blood Research and Development Program (BR&D) provides funding that supports researchers conducting important research projects on blood safety and effectiveness. This has led to significant advancements that will contribute to the maintenance of a safe supply of blood and blood products in Canada.

There is evidence that BR&D has supported Canadian Blood Services (CBS) in training many highly qualified personnel in transfusion science and medicine, funding research to enhance the safety and effectiveness in the blood system, establishing research networks to foster collaboration, and developing and maintaining learning opportunities for blood researchers. CBS and their funded researchers have also focused on identifying emerging issues and on

designing their research program to address those most pressing for Canadians. Most notably, there was significant policy and regulatory work undertaken in the past five years that led to lifting the donor deferral for men who have sex with men (MSM), and move to a behaviour-based screening questionnaire for all potential donors, which was supported by program research evidence.

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## Areas of Consideration

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No significant areas of concern were identified. Considering the success of the BR&D Program to date, the evaluation did not identify any recommendations. Instead, the evaluation has identified two areas of consideration for continuous improvement of this program.

**Canadian Blood Services' BR&D Program** should consider broadening knowledge dissemination strategies to help ensure that a range of communication media and methods are used to reach as many researchers and physicians as possible.

**Health Canada** should consider participating as an “observer” in meetings between Canadian Blood Services' BR&D Program and the research community in an effort to ensure that information is shared in an efficient manner.

## 1.0 Program Description

### 1.1 Program Context

Blood safety was recognized as a major issue in Canada following the contamination of the Canadian blood supply with Human Immunodeficiency Virus (HIV) and Hepatitis C virus, from the late 1970s throughout the 1980s, which resulted in the public health crisis known as the “tainted blood scandal”. As a result, the Government of Canada established the Commission of Inquiry on the Blood System in Canada (also called the Krever Inquiry). The Krever Report was tabled in the House of Commons in 1997, and set out a series of recommendations that continue to guide improvements in the blood system in Canada.

Krever’s twenty-fourth recommendation stated that the national blood service should have the facilities and the competence to conduct in-house research and development, as well as to conduct collaborative work between the national blood service and other organizations. In late 1997, a Memorandum of Understanding (MOU) between the federal government and the provinces and territories was signed to create the interim National Blood Authority. This MOU also committed \$5 million per year ongoing in support of blood research and development activities. When Canadian Blood Services (CBS) was created in September 1998, it inherited the mandate for coordinating a national research and development program (outside of Quebec).<sup>i</sup>

Through Health Canada’s (HC) Organs, Tissues and Blood Program, within the Strategic Policy Branch, the Government of Canada supports research that contributes to a safe and effective supply of blood and blood products for Canadians. Specifically, HC funds CBS in support of the BR&D Program for basic, applied, and clinical research on blood safety and effectiveness. BR&D activities centre on the following:

- **Funding priority research and development programs and projects.** This includes developing and implementing an R&D program that is expected to lead to new discoveries in areas that are relevant and timely for the blood system, identifying priority areas and projects to be funded, and monitoring and evaluating projects.
- **Engaging in knowledge mobilization (translation and exchange) from creator to user.** This includes developing and implementing a set of coordinated initiatives to develop and exchange knowledge that will enhance the capacity of researchers, health care professionals, staff in blood system service operations, and policy makers. It also includes a commercialization strategy to facilitate the translation of research findings into new products.
- **Training highly qualified personnel and building a transfusion science and medicine community of experts.** This includes developing and implementing training programs for highly qualified personnel, providing operational funding to other blood and transfusion medicine research programs to leverage talent and infrastructure, and build capacity in the field.
- **Facilitating collaborative working relationships.** This includes leveraging and advancing collaborations with national and international partners, including other blood operators, universities, hospitals, and industry, in order to translate discoveries into changes in practice and policy.

It should also be noted that Health Canada regulates the safety of collected blood and plasma, as well as blood and plasma-products through the *Blood Regulations* and *Food and Drugs Act*. CBS and HQ work to ensure patients have reliable access to safe and high-quality blood, plasma, stem cells, and organs and tissues. The Public Health Agency of Canada (PHAC) monitors adverse events within Canada associated with the transfusion of blood and blood products, as well as cell, organ, and tissue transplantation. Appendix 3 presents a

summary of roles related to the national blood safety system in Canada.

The \$5M ongoing funding has been unchanged in the last 22 years, beyond the blood deferral research related to men who have sex with men (MSM), which totalled an additional \$5.4 million over fiscal years 2016-17 to 2021-22. Appendix 1 presents a more detailed discussion of program budgets and expenditures.

## 2.0 Evaluation Approach

### 2.1 Evaluation Scope

The evaluation focused primarily on the impact of HC's funding for CBS' BR&D Program in supporting the safety of Canada's blood supply system, and covered activities from 2017-18 to 2021-22.

The evaluation used multiple lines of evidence, both qualitative and quantitative, to ensure triangulation of findings. These included a literature and document review, key informant interviews, and a comparison of surveillance systems from other countries. See Appendix 2 for detailed methodology, limitations, and mitigation strategies.

The evaluation was undertaken in fulfillment of the requirements of the *Financial Administration Act* and the Treasury Board of Canada's *Policy on Results* (2016).

### 2.2 Evaluation Questions

Attention was given to the impact of program activities on ensuring blood and blood product safety, quality, and supply, as well as examining challenges and barriers, along with emerging issues and opportunities that could be considered moving forward.

### Evaluation Questions

1. What has been the contribution of HC's BR&D Program to ensuring the safety, quality and supply of blood and blood products?
2. What is working well and what are the challenges and barriers? What emerging issues and opportunities should be considered moving forward?

## 3.0 Impact, Usefulness, and Relevance of BR&D

**HC's BR&D Program has supported CBS to fund research and development (R&D) projects to enhance the safety and effectiveness of the blood system, including blood safety projects, researcher learning opportunities, and knowledge dissemination.**

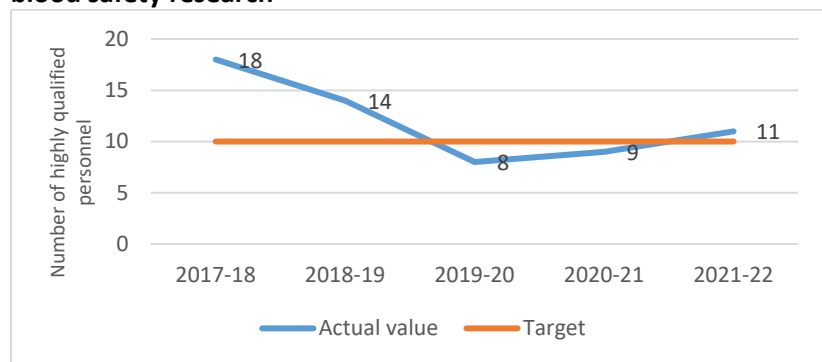
### 3.1 Highly qualified personnel participate in transfusion science and medicine in Canada

The Blood R&D Program has supported the training of highly qualified personnel in transfusion science and medicine through a graduate fellowship program, a post-doctoral fellowship program, and a transfusion medicine residency program. In addition, BR&D provides training positions in its internal research laboratories as well as external laboratories through its competitive research programs.

Figure 1 below presents the number of HQP who completed their training in blood safety research with CBS support through either the graduate fellowship program, the post-doctoral fellowship program, or the transfusion medicine residency program. During the

evaluation period, 60 trainees completed their training. This allowed individuals to strengthen their research skills and provided an opportunity to keep up-to-date with blood research practices, as well as building capacity by training new researchers. Furthermore, between 2018-19 and 2021-22, an average of 57 CBS competitive research awards were provided annually to research teams in academic settings to leverage talent and infrastructure, as well as to build blood safety capacity. Finally, the 11 CBS research laboratories also provide training supports to their highly qualified personnel.

**Figure 1: Number of highly qualified personnel provided training in blood safety research**



### 3.2 Key stakeholders in the transfusion community are knowledgeable

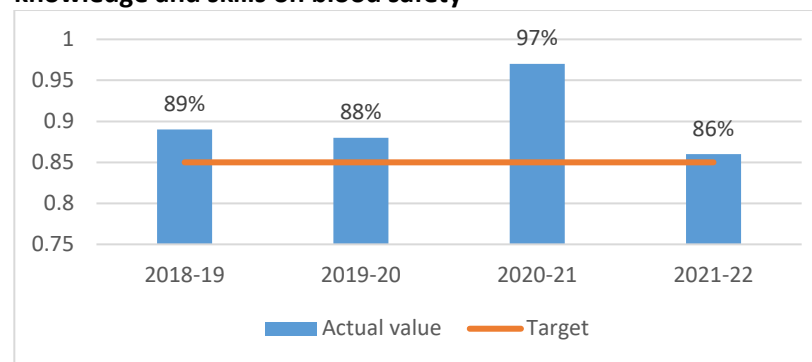
The vast majority of respondents consider themselves to be equipped with the knowledge and skills required to enhance blood safety in their field, as outlined in annual stakeholder surveys. BR&D funded knowledge is shared through peer-reviewed journal articles, conference presentations, collaboration on research grants, and communication from various organizations, including CBS and the National Advisory Committee on Blood and Blood Products.

Between 2018-19 and 2021-22, the number of stakeholders attending various events led by or delivered in partnership with CBS on blood safety generally met the expected target of 3,500. These events include annual symposiums, monthly seminar series, and transfusion camps. Through these various events, CBS has been able to do the following:

- foster collaboration both within CBS and across its internal and external research networks;
- exchange knowledge by showcasing ongoing research initiatives; and
- provide a professional development opportunity for research staff and trainees.

Furthermore, through post-event surveys, most attendees reported that they acquired knowledge and skills on blood safety through these various events, as presented in figure 2 below.

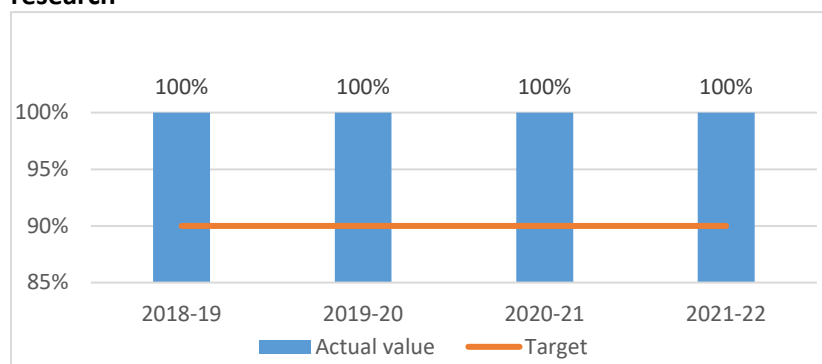
**Figure 2: Percentage of stakeholders reporting they have acquired knowledge and skills on blood safety**



### 3.3 Key stakeholders in the transfusion community apply knowledge created by R&D projects

The H-index captures the cumulative impact of an individual’s research through the number of times their work is cited by other researchers. Figure 3 below shows that all CBS blood safety researchers met the Canadian science or social sciences standards of a lifetime H-index (10.6 and 5.2 respectively), showing that other researchers within the transfusion community are using their work to advance knowledge and understanding.

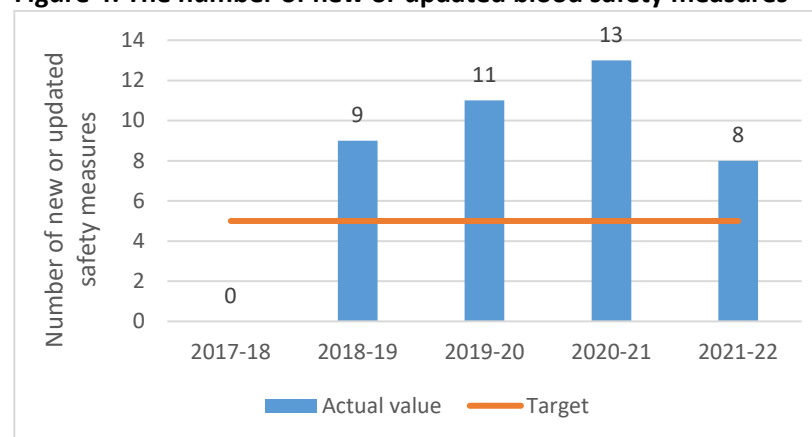
**Figure 3: Percentage of CBS blood safety researchers with a lifetime H-index that meets the Canadian science standard or the Canadian social science standard, depending on their area of research**



Most internal and external key informants also indicated that transfusion researchers inside and outside of Canada were working together when applying for grants or publishing. Duplication of effort was minimized, and the research community was updated on research taking place across the country, such as through the BR&D program collaboration with the Canadian Society for Transfusion Medicine.

Knowledge gained from research projects also led to well-informed policy. Between 2018-19 and 2021-22, CBS supported research that had a positive impact on improving blood safety measures from new evidence-based knowledge. As a result, over 40 new or updated blood safety measures have led to improvements in manufacturing processes, donor selection processes, as well as improved guidelines and policies (see figure 4). Most notably, there was significant policy and regulatory work undertaken in the past five years that led to lifting the donor deferral for men who have sex with men (MSM) and instead shift to a behaviour-based screening questionnaire for all potential donors. Moreover, BR&D-funded projects ensured the generation of adequate evidence-based research on alternative screening approaches for blood or plasma donors.

**Figure 4: The number of new or updated blood safety measures**



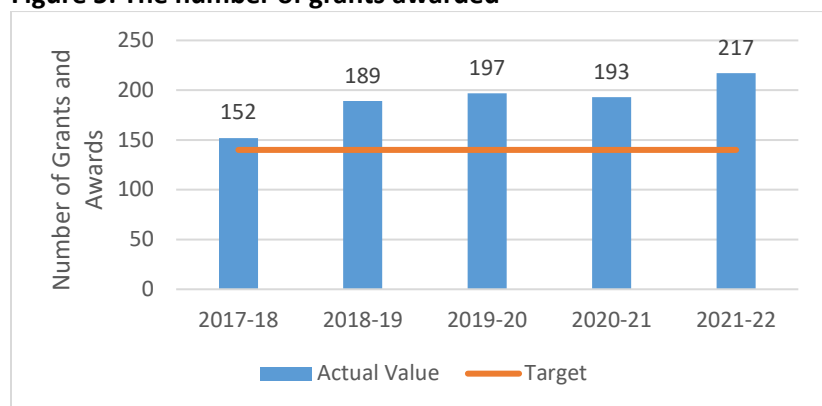
### 3.4 Research Awards and Network

Research awards are a core element of the BR&D Program, and the program provides funding for research both internal and external to CBS. CBS fostered a robust research network for both discovery and



development, and supported these areas through direct grants and various other mechanisms. The number of grants awarded is a metric that reflects the funding output that supports research through various programs. Figure 5 below shows the yearly combined total of grants CBS provided through national research programs, trainee fellowships, laboratory and group support, development programs, education programs, and clinical guideline development.

**Figure 5: The number of grants awarded**



### 3.5 MSM Research

In 2017, the Minister of Health’s mandate letter identified the need to develop a long-term vision for blood services that ensures safety and non-discrimination in donation policies. Then in 2019, the Minister of Health Mandate Letter specifically identified the need to work in partnership with CBS and HQ to build on existing progress to implement a behaviour-based model of donation that eliminates the blood ban for men who have sex with other men (MSM).

CBS did not have the necessary funding to expedite research in this area so the Government of Canada allocated \$3M in total in

additional funds to advance research aimed at further reducing barriers for MSM when donating blood. Budget 2019 provided an additional \$2.4M in total for similar activities but focussed on the donation of plasma. These funds flowed through the Organs, Tissues, and Blood program in Health Canada to amplify CBS’ research activities. With this funding, CBS accelerated research in this area and diversified its research streams. For example, CBS invested in social science which played a prominent role in generating evidence to reduce barriers for MSM. In 2019, and supported by evidence generated through the MSM research program, Health Canada authorized submissions from CBS and HQ to reduce the deferral period for MSM from 1 year to 3 months. In 2022, Health Canada authorized submissions from CBS and HQ to eliminate the blanket blood donor deferral for all sexually active MSM and to instead begin screening all donors, regardless of gender or sexuality, for high-risk sexual behaviour. These changes will be implemented by both blood operators by the end of 2022, signifying a shift towards more inclusive blood donation in Canada.

### 3.6 Emerging Issues, Challenges and Opportunities

**Evidence has identified a few potential emerging issues to the blood system and areas of improvement for the BR&D Program. These include understanding blood donor factors that affect the quality of stored blood products, and reviewing the adequacy of current dissemination mechanisms to ensure information is being shared with all potential stakeholders.**

There are still areas to address in the blood safety system. Studies are underway to understand blood donor factors that affect the quality of stored blood products. This should help optimize the quality of the blood components produced and provide a foundation for informing policies and future studies aimed at improving the safety and quality of blood transfusions.

CBS has also been supportive of work related to the recent COVID-19 pandemic. Specifically, CBS played a critical role in national Health Canada-approved clinical trials to determine if COVID-19 convalescent plasma could be a safe and effective treatment option for patients with the disease.

As another example of CBS' ongoing response to emerging issues, since the declaration by the World Health Organization of monkeypox as a public health emergency of international concern, CBS has had to change its donor screening questions and continues to monitor the evolving situation.

Most external key informants acknowledged the importance of continually seeking to improve knowledge dissemination strategies. CBS has made extensive use of social media platforms and the internet, which have worked well for the most part. In 2020-21 alone, there were close to 400,000 website visits to access information such as clinical guidelines, research publications, research summaries, and best practices. However, interviewees noted concerns about reliance on social media to reach researchers and physicians. This includes CBS' Professional Education Website and the Research Education Discovery blog. They mentioned that it would be important for CBS to expand its use of more traditional dissemination methods to reach all individual researchers, such as peer-to-peer information sharing.

While evidence suggests that Health Canada is kept well informed and remains engaged with CBS, internal and external interviewees identified an opportunity for Health Canada to participate as an "observer" in meetings between CBS and the research community to ensure the Department remains up-to-date on the latest information coming from the research and development world

pertaining to blood and blood safety, which can then be shared with partners within the Health Portfolio.

### 3.7 Program Resources

**Static funding for the last twenty years has resulted in a situation where CBS has less purchasing power when funding, given inflation. This may have affected the extent to which CBS was able to support basic, applied, and clinical research on blood safety and effectiveness.**

BR&D Program has funded activities to support research that contributes to a safe and effective supply of blood and blood products for Canadians. Indeed, the majority of federal funding goes to the internal discovery research laboratories and the competitive research programs in support of a national Canadian blood research network. Furthermore, in 2016-17 and 2019-20, the federal government topped up the annual contribution on a time-limited basis for blood deferral research related to men who have sex with men (MSM), which totalled an additional \$5.4 million over fiscal years 2016-17 to 2021-22.

However, while CBS reports to Health Canada on a variety of metrics and key performance indicators, some areas are not fully supported by the \$5M in ongoing funding. The contribution budget for the BR&D Program has remained static for the last 22 years. CBS has consistently delivered on outputs and outcomes despite the shrinking value of funding due to inflation (\$5M in 1998 would be worth approximately \$3M today).<sup>ii</sup> Thus, the purchasing power of this funding has steadily decreased. With the devaluing of the investment over time, CBS had to make difficult decisions in determining allocation of funds. For example, in recent years, federal funding that supported graduate fellowships had to support other areas. The development and sharing of clinical guidelines and

best practices is another key area where federal funding is not sufficient to support the necessary activities. CBS has so far mitigated these issues by securing other sources of funding (e.g., Canadian Institute for Health Research), which are inconsistent, and therefore may not be a viable strategy to respond to emerging needs or to support the long-term safety of the blood safety system.

## 4.0 Conclusions

The Blood Research and Development Program (BR&D) provides funding that supports researchers conducting important research projects on blood safety and effectiveness. This has led to significant advancements that will contribute to the maintenance of a safe supply of blood and blood products in Canada.

There is evidence that BR&D has supported Canadian Blood Services (CBS) in training many highly qualified personnel in transfusion science and medicine, funding research to enhance the safety and effectiveness in the blood system, establishing research networks to foster collaboration, and developing and maintaining learning opportunities for blood researchers. CBS and their funded researchers have also focused on identifying emerging issues and on designing their research program to address those most pressing for Canadians. Most notably, there was significant policy and regulatory work undertaken in the past five years that led to lifting the donor deferral for men who have sex with men (MSM), and move to a behaviour-based screening questionnaire for all potential donors, which was supported by program research evidence.

## 5.0 Areas of Consideration

With the noted success of the BR&D Program to date, and that no significant issues were identified, the evaluation did not identify any recommendations. Instead, the evaluation has identified two areas of consideration for continuous improvement of this program.

**Canadian Blood Services' BR&D Program should consider broadening knowledge dissemination strategies to help ensure that a range of communication media and methods are used to reach as many researchers and physicians as possible.**

While dissemination strategies are working well, there could be some additional improvements made by broadening the range of communication tactics to reach a wider audience of researchers and physicians who may not consistently review Canadian Blood Services' website or social media.

**Health Canada should consider participating as an "observer" in meetings between Canadian Blood Services' BR&D Program and the research community in an effort to ensure that information is shared in an efficient manner.**

The evaluation also found that there are opportunities for Health Canada to participate as an "observer" in meetings between Canadian Blood Services and the research community to remain aware of the latest blood safety research activities, and to share these with partners within the Health Portfolio.

## Appendix 1: Budget and Actual Expenditures

The table below outlines budgets and expenditures for grants and contributions on the Blood Research and Development Program’s activities to support research that contributes to a safe and effective supply of blood and blood products for Canadians. The variance between budgetary allotments and expenditures is also provided. This information is divided by fiscal years between 2017-18 and 2021-22.

Between 2017-18 and 2021-22, an annual budget of \$5 million was allocated to the Blood Research and Development Program in contributions to support CBS’ research activities. Additionally, in 2016-17 and 2019-20, the federal government topped up the annual contribution on a time-limited basis for blood deferral research related to men who have sex with men (MSM), which totalled an additional \$5.4 million over fiscal years 2016-17 to 2021-22 (this includes a disbursement of \$175,000 in 2016-17).

Salary and O&M to support the Organs, Tissues and Blood Program is funded separately from the G&C funding provided to CBS for the BR&D Program. Additionally, following Treasury Board approval in 2020 of a merger that created the new Organs, Tissues, and Blood Program, financial data on salary and O&M are not disaggregated between the BR&D component and the Organs and Tissues Donation and Transplantation component.

Furthermore, there is no dedicated source of funds for the administration and management of the BR&D component or Organs, Tissues, and Blood Program as a whole – salary and O&M funding is provided by the Strategic Policy Branch of Health Canada. At present, one dedicated full-time employee (EC-0 at .9 full-time equivalent), alongside partial support from a manager (EC-07 at .25 full-time equivalent) and a program advisor (PM-05 at .5 full-time equivalent) maintain program activity streams such as policy work, BR&D monitoring, liaison and coordination with provinces and territories, and further strategic investments. Costs related to managing the contribution agreement with CBS, as well as policy and liaison support related to this initiative have been absorbed within existing Health Canada reference levels.

Expenditures	Budget (\$)		Actual (\$)		Variance (\$)	% Budget Spent
	G&Cs: BR&D	G&Cs: blood deferral research related to MSM	G&Cs: BR&D	G&Cs: blood deferral research related to MSM		
<b>2017-18</b>	\$5,000,000	\$1,250,000	\$5,000,000	\$1,250,000	\$0	100%
<b>2018-19</b>	\$5,000,000	\$1,250,000	\$5,000,000	\$1,250,000	\$0	100%
<b>2019-20</b>	\$5,000,000	\$700,000	\$5,000,000	\$1,025,000	\$325,000	105.7%
<b>2020-21</b>	\$5,000,000	\$1,500,000	\$5,000,000	\$1,500,000	\$0	100%
<b>2021-22</b>	\$5,000,000	\$200,000	\$5,000,000	\$200,000	\$0	100%
<b>Total</b>	<b>\$25,000,000</b>	<b>4,900,000</b>	<b>\$25,000,000</b>	<b>\$5,225,000</b>	<b>\$325,000</b>	

## Appendix 2: Evaluation Approach and Limitations

### Approach

The purpose of the evaluation was to examine the impact of Health Canada’s BR&D component in supporting the safety of Canada’s blood supply system. The Organ and Tissue Donation and Transplantation component was not evaluated at this time as a decision was made to focus on the blood programs within Health Canada.

Data was collected and analyzed through various methods, as outlined below. These lines of evidence were also analyzed by triangulation to improve the reliability and credibility of evaluation findings and conclusions.

The evaluation examined the following key questions:

1. What has been the contribution of HC’s BR&D Program to ensuring the safety, quality, and supply of blood and blood products?
2. What is working well and what are the challenges and barriers? What emerging issues and opportunities should be considered moving forward?

### Methodology

Data for this engagement was collected using the following methods:

#### INTERVIEWS

Conducted interviews with 22 representatives from the following groups:

- 6 HC staff and management;
- 10 representatives from the Canadian Blood Services and funded researchers; and
- 6 provincial or territorial representatives.



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#### DOCUMENT REVIEW

Reviewed approximately 120 documents and files, including administrative files, contribution agreements, records of decisions, online publications, case study reports, and briefing materials.



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#### DATA ANALYSIS

Examined program performance information, including annual program performance reports.



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#### FINANCIAL DATA REVIEW

Examined the financial costs of delivering activities at Health Canada’s Strategic Policy Branch.

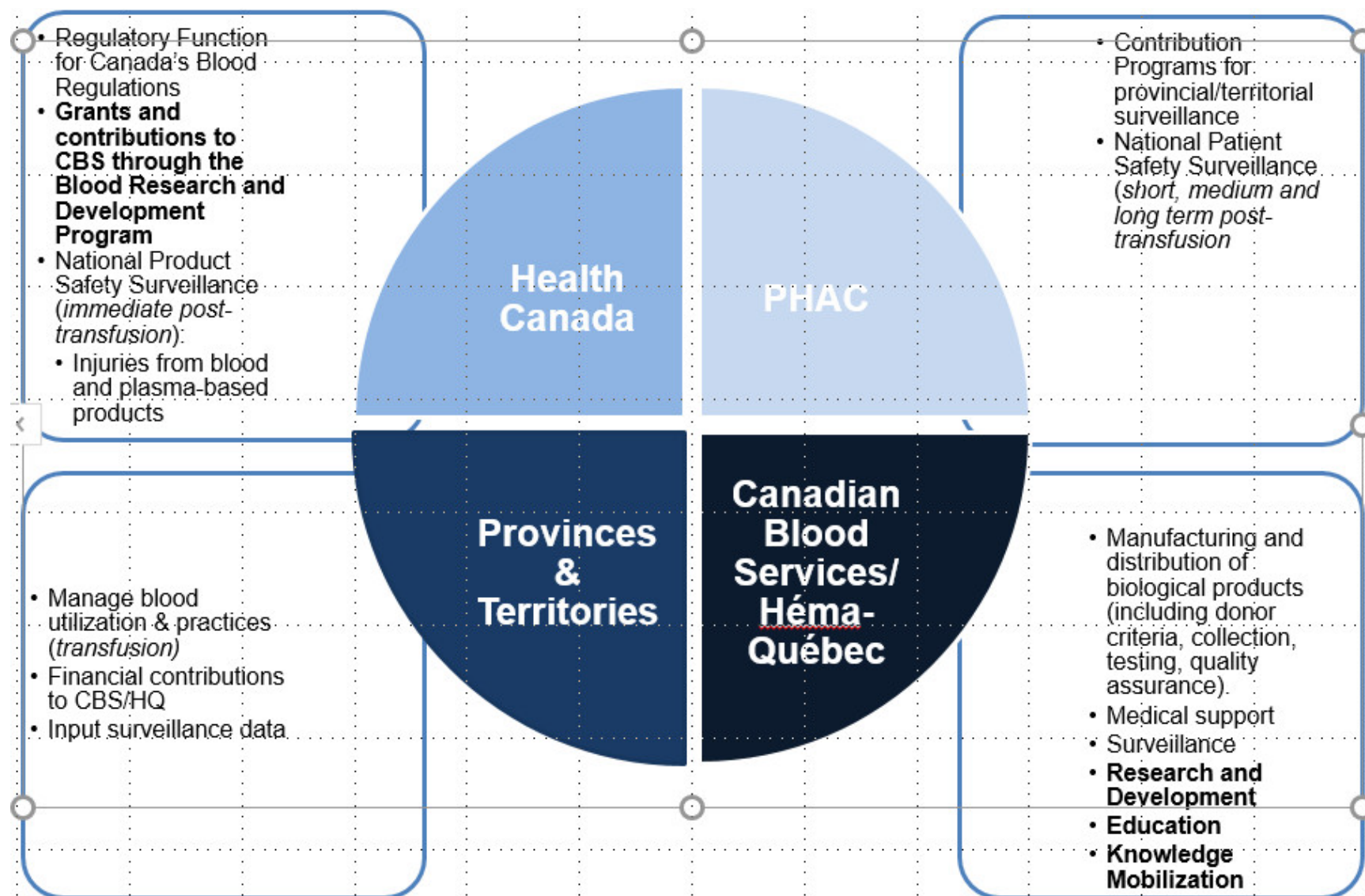


### Limitations

The following table outlines the limitations encountered during the implementation of the data collection methods selected for this evaluation, although it should be noted that the evaluation did not encounter any significant methodological issues. Also noted are the mitigation strategies implemented to ensure that evaluation findings could be used with confidence in guiding program planning and decision making.

Limitation	Impact	Mitigation Strategy
Interviews with internal staff and external stakeholders are retrospective in nature. This may lead to the provision of recent perspectives on past events.	This can affect the validity of assessing activities or results relating to improvements in the program area.	Triangulation of other lines of evidence was used to substantiate or provide further information on data received through the interviews.

## Appendix 3: National Blood Safety System in Canada



## End Notes

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<sup>i</sup> It is important to note that Héma-Québec (HQ) was also created in 1998 to supply blood and other biological products of human origin to hospitals for Quebec. CBS has a unique relationship with HQ, as the two organizations work closely to share blood products in times of need and collaborate regularly to share information, insights, and data.

<sup>ii</sup> Based on calculations undertaken through the Bank of Canada Inflation Calculator: <https://www.bankofcanada.ca/rates/related/inflation-calculator/>.