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LOOKING TO THE FUTURE

2023 Scientific Activities Report

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Research organizational structure at Héma-Québec

Scientific activities are labelled with the below icons, which indicate the type of product to which they pertain.



Scientific activities related to this year's highlights, that is COVID-19 and the inclusivity of blood donation, are labelled with the below icons.



COVID-19



Inclusivity of blood donation

MESSAGE FROM THE VICE PRESIDENTS

Dear reader,

It is a privilege to present to you the 2023 edition of Héma-Québec's Scientific Activities Report, whose publication coincides with the 25th anniversary of our organization. To mark this major milestone, the first pages of the report give an overview of the evolution of Héma-Québec's research activities over the past 25 years.

This edition also provides an opportunity to celebrate another anniversary that holds a special place in our hearts, namely Renée Bazin's 35 years of service. Renée began her career at the Canadian Red Cross prior to the transfer of blood collection and product distribution to Héma-Québec in 1998. She subsequently worked as director of innovation (from 1999 to 2020), and then as Héma-Québec's scientific director (since 2020). We are pleased to recognize her competency and unconditional commitment to the mission of our organization over all these years.

True to form, the report also provides an overview of the remarkable work carried out by the teams of the Vice-présidence aux affaires médicales et à l'innovation (VP-AMI) and the Vice-présidence à la médecine transfusionnelle (VP-MT). The scientific achievements of 2023 have contributed to strengthening Héma-Québec's position as a leader in the field of research and innovation, something that we are very proud of.

Over the course of 2023, our teams undertook several projects consistent with our goal of making the donation of blood products more inclusive. This work paved the way to the withdrawal of the deferral criterion regarding variant Creutzfeldt-Jakob disease, which came about in December following approval by Health Canada. In the same vein, Héma-Québec continues to assess the effects of expanding the eligibility to donate blood products to men who have sex with men (MSM), a major change that came into effect in 2022.

Several of our achievements have also improved, or are improving, the health of the Québec population. Four new patients with ligneous conjunctivitis — a rare genetic condition that can lead to blindness — are benefiting from plasminogen eye drops produced by Héma-Québec. Given this growing need, we are on track to transition from an experimental production to an ongoing and standardized production. Our teams are also working on developing a new method to isolate and collect granulocytes — a product that is transfused to certain immunosuppressed patients. Ultimately, this method will make it possible to add value to a byproduct, i.e., residual leukocytes, that is usually rejected. The year 2023 also marked the official launch of our rare blood program in partnership with hospitals. The program has enabled Héma-Québec to better serve the needs of recipients for whom the pool of compatible donors is more limited.



Finally, the past year has showcased Héma-Québec's vital role in training and disseminating knowledge about transfusion medicine. Two symposia were organized: the first dealing with international practices regarding eligibility criteria for blood product donation by MSM, and the second addressing the opportunities and challenges of cell therapy and regenerative medicine (a collaboration with ThéCell). Héma-Québec also took part in drafting a guide on the best practices to be adopted in a blood bank laboratory. This guide will surely become an invaluable tool for the entire immunohematology community in Québec. In 2023, our organization also trained many students, researchers and clinicians, several of whom have been recognized for the quality of their work.

Héma-Québec's scientific activities are made possible largely thanks to the generosity of the persons who consented to donate biological products. We extend our warmest thanks to their vital contribution to improving health care in Québec.

These achievements, along with those of the past 25 years, are a testament to the vitality of the VP-AMI and VP-TM and underscore the prominent role played by research and development in Héma-Québec's past, present and future.

Dr. Marc Germain, MD, FRCPC, Ph.D.

Dr. Nancy Robitaille, MD, FRCPC Vice-President, Medical Affairs and Innovation Vice-President, Transfusion Medecine

HIGHLIGHTS

Training and knowledge sharing

Yelena Boccacci, a PhD student who conducted her thesis work at Héma-Québec, **earned a place on the Dean's Honour Roll of the Université Laval's Faculty of Medicine** for the quality of her thesis.

>

Héma-Québec held **an international symposium on the new eligibility criteria** for men who have sex with men, in collaboration with <u>Canadian</u> <u>Blood Services</u> (CBS)

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Another symposium was organized jointly with the <u>Réseau de thérapie</u> <u>cellulaire, tissulaire et génique du Québec</u> (ThéCell) to underscore the challenges and opportunities related to cell therapy and regenerative medicine in Québec.

Héma-Québec contributed to **the first edition of an immunohematology guide** intended for staff working in hospital blood bank laboratories.

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Héma-Québec's **rare blood program** was officially launched in June 2023.



The deferral criterion related to variant Creutzfeldt-Jakob disease was lifted,

thanks in large part to research conducted by Héma-Québec.

Four new patients with ligneous conjunctivitis — a rare condition that can lead to blindness —

are now benefiting from eye drops made of plasminogen concentrate prepared by Héma-Québec.

An international study involving the participation of Héma-Québec highlighted the quality parameters of red blood cells from teenage and senior donors. Héma-Québec continued developing **an isolation method for granulocytes**

that will add value to a byproduct that is currently rejected.

25 YEARS OF RESEARCH AT HEMA-QUEBEC

1998 **Start of research** and development

operations

1999

Creation of a research group in charge of evaluating and optimizing the products, processes and operations

2003

Development of an in-house screening test for West Nile virus and use for testing blood products — a first in Canada!

2017

Merging of the Vice-présidence à la recherche et au développement and the Vice-présidence aux affaires médicales — a reorganization that gave birth to the Vice-présidence aux affaires médicales et à l'innovation and the Vice-présidence à la médecine transfusionnelle





2018

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Establishment of GoPAMI²: a committee in charge of evaluating the projects submitted by scientific staff

2013

Production of plasminogen eye drops for the treatment of ligneous conjunctivitis — an innovation awarded a prize from the ADRIQ¹

0000 ZUZU

Resumption of the CCSM³ meetings — a committee that advises the advisory board on scientific progress, evaluates projects, and monitors the implementation of procedures and policies in research and development



2004

Relocation of the research activities in a new building on the campus of Université Laval



2007

Launch of a mass genotyping program for blood donors, thanks to a partnership with Génome Québec



Participation in COVID-19-related studies, in collaboration with the INSPQ⁴ and many other academic research partners





HEALTH OF QUĒBEC'S Population

"The work carried out in erythrocyte immunology involves gathering and interpreting data like an investigator. Some of these clues are obtained thanks to the invaluable support of the research teams that conduct specialized analyses. Everyone works efficiently and rigorously to ensure that our expertise and innovation benefits the Québec population!"

Nadia Baillargeon, TM

Senior Specialist in Erythrocyte Immunology



Health of Québec's population

Innovation

Product safety and efficacy, and donor safety

Support to operations

Training and knowledge dissemination

Héma-Québec's research and development activities have resulted in concrete benefits for the health of the public. Several projects carried out in 2023 have contributed to improving the health of Québecers.

First edition of an immunohematology guide

Transfusion medicine is a complex discipline: the least false move can translate into serious consequences for the health of recipients. It is imperative, therefore, for strict quality criteria to be adopted in a hospital blood bank laboratory.

The year 2023 was marked by the publication of the first edition of an immunohematology guide drafted jointly by the Ordre professionnel des technologistes médicaux du Québec (OPTMQ), the Association professionnelle des chargés de sécurité transfusionnelle du Québec (APCSTQ) and Héma-Québec, with the collaboration of several physicians from the Association des médecins hématologues et oncologues du Québec (AMHOQ). The purpose of this guide is to strengthen the quality and safety criteria that apply to activities carried out in a blood bank laboratory. The guide presents safe and consistent transfusion practices, compiles recommendations for procedures not regulated by current law, and provides solutions for problems commonly encountered during testing in blood banks, ranging from interpreting results to managing blood products.

This work, available <u>here</u>, will guide medical technologists so that they can exercise their professional judgment while strictly applying established policies and procedures.

The immunohematology guide aims to strengthen the quality and safety criteria that apply to activities carried out in a blood bank laboratory.

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Plasminogen eye drops prepared by Héma-Québec In 2013, Héma-Québec developed a process to manufacture eye drops made of plasminogen concentrate for patients with ligneous conjunctivitis.

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Innovation

Nuno Catalog #

Product safety and efficacy, and donor safety

Support to operations

Training and knowledge dissemination

Launch of the rare blood program

An individual's blood group is deemed rare if it is found in fewer than one in 1,000 individuals in the general population. Persons with rare blood can be identified following a blood test at the hospital, e.g. testing as part of pregnancy follow-up. These patients are then referred to Héma-Québec to confirm their rare blood status and, where appropriate, to find compatible rare blood donors.

Finding a compatible rare blood donor may become a race against time. An immediate or delayed adverse reaction can occur in a person with a rare blood who receives a unit of regular (even O negative) blood if that person has previously developed antibodies directed against certain antigens at the surface of red blood cells. For some patients, their blood is so rare that it is necessary to consult several overseas partners to find compatible blood, which can take weeks.

Héma-Québec hopes to diversify its rare blood bank, which currently holds some 2,000 units of frozen packed red blood cells of several types of rare blood. To this end, the organization officially launched its rare blood program in June 2023. The objective is to collaborate with clinicians to raise awareness among patients with rare blood and encourage them to communicate with Héma-Québec to donate blood and take part in a family study. By optimizing its rare blood bank, Héma-Québec hopes to meet the demand for rare blood units more quickly by using blood collected at its own donor centres.

Treating ligneous conjunctivitis with plasminogen eye drops prepared by Héma-Québec

Ligneous conjunctivitis is a condition caused by plasminogen deficiency. It is characterized by the formation of fibrin-rich membranes on the eyelids. Left untreated, this condition can lead to blindness. In 2013, Héma-Québec developed a process to manufacture eye drops made of plasminogen concentrate for a young boy who was not responding to conventional treatments. These eye drops quickly improved the patient's condition, and he continues to benefit from them today to prevent the formation of membranes on his eyes.

In October 2022, a physician made a request to administer these eye drops to another 11-month-old patient who also had plasminogen deficiency. With the authorization from Health Canada, Héma-Québec was able to quickly provide eye drops to the patient, just in time for his first birthday. In 2023, Héma-Québec received requests for three other patients, bringing to five the number of young Québecers now benefiting from this plasma derivative, purified and bottled by Héma-Québec.

Immediate hemolytic reactions in recipients transfused with potentially incompatible A3 blood

Some group A donors have so few A antigens on the surface of their red blood cells that they can be assigned to group O (because of fluctuations in anti-A1 levels in their plasma). Each year, up to 10 new donors with weak A blood are identified — whereas they had been previously identified as group O or B donors. The effects of a transfusion of weak A blood to group O or B recipients are unknown.

The goal of this project was to evaluate the incidence of acute hemolytic transfusion reactions (AHTR) in group O or B recipients who were transfused with weak A blood. The transfusion safety officers, who work in hospitals, retrospectively collected AHTR indicators in 81 group O or B patients who could have been susceptible to develop an AHTR as they received A3 blood (i.e. the most common weak A subgroup) from nine donors. Reassuringly, the interpretable data did not show any evidence of an AHTR.

Following the assessment of these data, Health Canada authorized Héma-Québec not to notify hospitals when a donor with a weak A or B phenotype is identified after donating. These donors are now redirected to source plasma donation. These data were published in an article in the journal Vox Sanguinis.

Prevalence and predictors of anemia in children following a hospital stay in intensive care

In recent years, the hemoglobin levels justifying a transfusion have been revised downward. As a result, fewer children admitted to intensive care are transfused, and several are anemic when released from hospital. However, the scope of this potential problem is unknown.

The aim of this study, conducted at the <u>Centre hospitalier universitaire Sainte-Justine</u> (CHU Sainte-Justine), in collaboration with Héma-Québec, was to study the epidemiology of anemia in children released from hospital after a stay in intensive care. A total of 51% of children who were released were anemic when leaving hospital. Anemia was also frequent in patients who had undergone cardiac surgery for acyanotic heart disease (53%). The presence of anemia at admission was the strongest predictor of anemia at the time of release.

Approximately half of the children are anemic upon being released from an intensive care unit. Other studies are needed to understand the effects of this condition on the children's development. This project was the subject of a study published in the journal *Transfusion*.

A cannabinoid mixture alters the function of B cells

Some data suggest that consuming cannabis could alter the immune response, raising concerns because of increased cannabis consumption in Canada.

This study, carried out in collaboration with the Université Laval and Imam Mohammad Ibn Saud Islamic University, assessed the effect of a cannabinoid mixture (CM) on B lymphocytes and explored the mechanisms by which a CM exerts its potential anti-inflammatory properties. The CM

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Approximately

of children are anemic upon being released from an intensive care unit.

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had a dose-dependent, cytotoxic effect on B lymphocytes — a phenomenon mediated by apoptosis. Exposure to the CM caused DNA damage, reduced the mitochondrial membrane potential, and increased the levels of reactive oxygen derivatives and activated caspases. Moreover, exposure to the CM reduced the activation of the ERK1/2, NF-kB, STAT5 and p38 pathways, and the number of cells expressing IgMs and IgGs. Finally, exposure to the CM significantly altered the profile of the cytokines released by B lymphocytes.

These results suggest that cannabinoids have a harmful effect on B lymphocytes by inducing their death through apoptosis, which was primarily mediated by the caspase pathway. The results of this study were published in the journal <u>Cells</u>.

A population study of the genetic profile of HLAs in Québec

Selecting compatible donors for the human leucocyte antigen (HLA) is vital for hematopoietic stem cell (HSC) transplantation. The absence of high-resolution data on HLAs in the Québec population complicates high-level decision making for HSC donor research.

The aim of this study was to analyze the HLA data of individuals enrolled in Héma-Québec's HSC donor registry. The HLA data were acquired at the second-field resolution by next-generation or Sanger sequencing. Statistical tools were used to analyze these data, and the HLA of most regions in Québec were able to be determined. Some regions presented characteristics between them that reflected the demographic changes that occurred in Québec, from colonization to the present.

The identification of Québec HLAs carried out as part of this study enhanced the available information and improved decision making related to HSC transplantation. The data from this study were published in the journal <u>HLA</u>.

Blood antigens associated with SARS-CoV-2 in Québec



At the start of the COVID-19 pandemic, some data suggested that the risk of infection from SARS-CoV-2 was lower in group O individuals. Likewise, some HLA alleles seemed associated with a higher or lower risk of infection. However, these potential risk factors for COVID-19 currently remain ill-documented, which limits our ability to better manage the disease.

The objective of this study was to determine the blood antigens that increase the risk of COVID-19. Two groups were included in the study: 1) convalescent plasma donors who had contracted SARS-CoV-2 (without being hospitalized); and 2) control donors from the registries of the National Marrow Donor Program (NMDP) and Héma-Québec. Sequencing and phenotyping technologies were used to determine the blood antigens and HLAs, and statistical tools were used to analyze these HLAs. In the end, AB and Fy*A red blood cell antigens were overrepresented among the convalescent individuals. Likewise, eight HLA alleles had a higher prevalence than expected among convalescent individuals.

Product safety and efficacy, and donor safety

Support to operations

Training and knowledge dissemination

An Héma-Québec study identified the HLAs of the **Québec population, thus** expanding the current knowledge and informing decisions related to the transplantation of hematopoietic stem cells.

Outreach

Research partners

Funding



Several red blood cell antigens and HLA alleles seem to predispose certain individuals to COVID-19. These risk factors could guide the clinical management of patients with COVID-19 and the prevention strategies to address it. These results were published in the journal *Future Virology*.

Prevalence of weak D phenotypes in Québec

Some people exhibit an atypical (i.e. "weak") Rh phenotype, which can be broken down into several subvariants. In Québec, weak D type 42 is the most common Rh subvariant, while weak D types 1, 2 and 3 are generally predominant in other populations similar to that of Québec. However, the exact prevalence of weak D type 42 in the Québec population remains unknown.

This study, carried out with data from the <u>CARTaGENE</u> platform, assessed the prevalence of this phenotype in the general population using a genetic approach. This was done by screening for the RHD*01W.42 allele (associated with the D42 phenotype) in 1,000 CARTaGENE participants, a cohort representative of the adult population of Québec. Two persons were carriers of this allele. Based on this result, the prevalence of weak D type 42 was estimated to be 0.08% in the Québec population.

Based on this finding, Québec has the highest prevalence of weak D type 42 documented to date. These results were published in the journal <u>Vox Sanguinis</u>.

Evaluation of service offers and techniques under development for non-invasive prenatal screening of platelet antigens

Fetal and neonatal alloimmune thrombocytopenia (FNAIT) is a disease of the fetus that occurs when a pregnant woman becomes alloimmunized against fetal platelet antigens. Several pregnant women could benefit from stricter follow-up for this disease if a screening tool were available for early diagnosis.

The objective of this project was to identify non-invasive prenatal genetic screening tools (NIPST) for platelet antigens and initiate discussion of Héma-Québec's positioning on this type of analysis. The project revealed that an NIPST service is offered in some overseas laboratories, but that the offer is limited. No service of this kind exists in North America. As for the methods used, they can be grouped into three types of technologies, but no commercial kit is currently available.

Many pregnant women would benefit from a closer monitoring for fetal and neonatal alloimmune thrombocytopenia if a screening tool allowed for an earlier diagnosis of this condition.

Training and knowledge

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The sharing of samples, technologies and expertises on the characterization of the immune response to SARS- CoV-2 led to numerous breakthroughs in 2023.

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Support to operations

Training and knowledge dissemination

This picture of NIPST tools retained two methods that could be adequate and eventually implemented at Héma-Québec. This project falls within the overall thinking about the directions to be taken by Héma-Québec regarding genetic analyses, with the aim of optimizing our products and offering patients increasingly specialized services.

Research projects on immunity to SARS-CoV-2

To quickly acquire knowledge about COVID-19, Héma-Québec's research teams pooled their efforts and expertise with those of the <u>Centre de recherche du Centre</u> <u>hospitalier de l'Université de Montréal</u> (CRCHUM), the <u>Université de Montréal</u> and <u>Yale University</u>. The sharing of samples, technologies and expertises on the characterization of the immune response to SARS- CoV-2 led to numerous breakthroughs in 2023.

Two studies assessed the humoral response to the spike protein of several variants, including BQ.1.1, in vaccinated and unvaccinated donors before and after they had contracted SARS-CoV-2. Another project analyzed the ability of an antibody to recognize the spike protein of several variants and to stimulate antibody-dependent cell-mediated cytotoxicity. Other works compared the results generated by two ELISAs (enzyme-linked immunosorbent assays) and assessed the humoral response to SARS-CoV-2 in non-hospitalized individuals. Finally, using a mouse model, a study evaluated how the neutralizing activities of convalescent plasma and Fc receptors influence the efficacy of convalescent plasma. Collectively, this work led to the publication of five articles (references 9, 18, 45, 46, 47).

Another contribution to public health

 Héma-Québec and <u>Canadian Blood Services</u> evaluated the acceptability of a pilot program launched in 2021. The program enabled the withdrawal of the 3-month deferral period for men who have sex with men. The data from this study were published in <u>BMC Public Health</u>.

Outreach

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INNOVATION

"Working as a research professional at Héma-Québec means leveraging innovative ideas for the organization. We feel that our research projects make a difference not only in day-to-day operations, but also in the advancement of the science of blood cells."

Mathieu Drouin, MSc

Research Professional



Héma-Québec brings innovative solutions to meet the challenges of transfusion medicine. The year 2023 saw a wealth of innovations of all kinds.

Development of a production method for granulocyte concentrates

Patients with low levels of neutrophils (i.e. neutropenia) are at risk of developing a lethal infection. To increase their levels of neutrophils, a transfusion of granulocyte concentrates (GCs) may be considered. Héma-Québec currently supplies apheresis GC products to hospitals in Canada. However, because of supply problems, Héma-Québec is seeking to develop a new way of producing its GCs. Our organization uses the automated Reveos[®] system to separate whole blood into three components. In the process, the device generates a bag of residual leukocytes (BRL) that is currently being discarded. The BRLs of several whole blood donations could be combined to form GCs for transfusion, making use of this byproduct.

The objective of this project is to develop a protocol for the production of GCs using BRLs generated by the automated Reveos[®] system and to assess the quality of the produced GCs. To this end, release tests currently in use (i.e. sterility and number of granulocytes per bag) will be verified. In parallel, biochemical tests (i.e. complete blood counts, lactate, glucose, pH), cell characterization tests by flow cytometry, and neutrophil function tests (i.e. chemotaxis, phagocytosis and reactive oxygen derivatives) will be conducted to fully characterize the GC products.

This project will enable the rapid transfer of a GC production method to operations and the delivery of a safe, quality product for Canadians in need.

Accessory-cell-free differentiation of hematopoietic stem cells into mature red blood cells

Protocols for the *in vitro* production of red blood cells are well documented. However, these protocols do not enable the production of red blood cells that are identical to those circulating in the human body, since the terminal maturation of reticulocytes into red blood cells remains incomplete.

The objective of this study was to develop a method to obtain mature red blood cells from adult hematopoietic stem cells, without accessory cells or compounds from animal sources. The approach that was developed makes it possible to obtain red blood cells of

Innovation

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Support to operations

Training and knowledge dissemination

A method has been developed to obtain mature red blood cells from adult hematopoietic stem cells, without any feeder cells, accessory cells and animal-derived components.

In-vitro-cultured red blood cells

Outreach

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Funding

unprecedented maturity, while improving cellular integrity and survival after enucleation. It also enables the storage of red blood cells for 42 days in a nutrient solution without specialized equipment, which is a significant logistical advantage.

This work is helping to improve the techniques used to produce red blood cells in vitro. This could prove useful in confirming the ability of gene therapies that are being developed to produce mature and functional red blood cells. This work was published in the journal <u>Cytotherapy</u>.

Development of a method to prepare leukoreduced red blood cells from a small volume of blood

Projects to optimize analytical methods require several blood donations. This can be complicated for the departments responsible for collecting and preparing the blood components. Such projects would be made much easier if the blood components could be obtained from a small volume of whole blood. This could also simplify the creation of experimental diagrams that combine biological materials with the goal of standardizing their composition. Currently, no experimental method exists to reproduce, in small volumes, the conditions for transforming a complete whole blood donation.

The aim of this project was to develop an experimental method that met regulatory standards and enabled the transformation of less tnan 25 ml of whole blood. The technical performance of commercial leukoreduction filters was compared to that of conventional devices used for the collection and processing of whole blood. A multifactorial experiment then identified the conditions needed to obtain a quality comparable to that of conventional products. In the end, the study determined the optimal processing conditions to prepare 9 ml of packed red blood cells from a whole blood donation of 24 ml collected in a tube. The hemoglobin and hematocrit levels, the percentage of leukoreduction, the residual concentration of platelets, and the rate of recovery of red blood cells all met regulatory standards.

The experimental method developed as part of this study makes it possible to generate quality red blood cells from a small volume of whole blood collected in tubes. This method is ideal for conducting future multi-parameter tests at Héma-Québec.

Characterization of the rapid freezing process (Blast Freezer) for plasma collected in bottles and destined for fractionation

A previous study by Héma-Québec showed that using rigid bottles offers major advantages for the collection of plasma by apheresis, in particular greater resistance to breakage and better recovery of the plasma during the fractionation process. The use of rigid bottles could facilitate the achievement of plasma self-sufficiency that Héma-Québec aims for.

Support to operations

The experimental method developed in this study enables the production of high-quality packed red blood cells from a small volume of blood collected in tubes.

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To better document the feasibility of such a change, our organization evaluated the effects of freezing plasma for fractionation in bottles in a ThermoFisher Blast Freezer (BF). The optimal operating conditions were determined to ensure that the internal temperature of the products reached -25 °C. To achieve this, the temperature of the bags and bottles containing 905 ml of a saline solution was measured in various freezing scenarios. The BFs could not contain more than 54 donations of plasma for fractionation because of their size and the vertical positioning of the bottles during freezing. The results showed that rigid bottles met the expectations and standards for the freezing of plasma for fractionation.

In conclusion, at the current rate of introduction of lots (i.e. 90 minutes per lot), freezing plasma for fractionation in bottles rather than bags meets the expectations and standards of Héma-Québec. However, the impact of the total capacity of the BF on operations needs to be studied in greater detail.



Optimization of a decellularization method for heart valves

Valves of human origin are often the best option for replacing heart valves. However, the transplant can be rejected by the recipient's immune system, requiring further surgery. Unlike solid organs, heart valves can perform their function for decades without the donor's cells surviving transplantation. Thus, the elimination of cells and other immunogenic materials — while preserving the physical characteristics of the heart valve — should reduce the risk of death, surgery and dysfunction caused by the recipient's immune system.

The aim of this project was to develop a method for decellularizing heart valves to make them immunologically inert, while preserving their functionality imparted by the native components of the extracellular matrix (ECM). The method that was developed extends over 14 days and consists of several steps: decontamination, cell lysis, washing with detergent, nuclease digestion and waste elimination. According to the biochemical, histological and immunohistochemical analyses, the optimized protocol eliminates all cells and more than 90% of the main biomarkers tested. It also preserves the properties of the ECM — including glycosaminoglycan retention, something that has never been reported before.

This decellularization protocol showed similar or slightly better results than those previously described in the literature. In a final phase, the protocol will be subjected to mechanical and hydrodynamic *in vitro* testing. The enthusiasm of Québec's cardiothoracic surgeons contributed to expediting the study, and transplantation trials are being planned in the coming year.

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The optimized decellularization protocol eliminates all cells and more than 90% of the main biomarkers tested, while preserving the properties of the extracellular matrix.

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Development of new shipping boxes adapted to Héma-Québec's cold chain needs

The biological products of human origin that are collected, processed, stored and distributed by Héma-Québec must be maintained at precise temperatures to optimize their quality and safety. When they must be exposed to uncontrolled temperatures, these products must be packed in boxes capable of maintaining their storage temperature. Given the extreme temperatures encountered in Québec, conventional packaging does not meet the requirements of regulatory agencies.



Héma-Québec undertook several projects to develop transportation solutions adapted to the needs of the requesting departments and the characteristics of the biological products involved. The development process consisted of several steps: 1) determining refrigerants (composition and quantity) conditioned to generate a thermal equilibrium at the target temperature, and 2) designing an outer insulation shell adjusted to meet the expectations of the requesting departments and regulatory standards. Several temperature control systems were developed, assessed and validated to meet the transportation and storage needs of the various product lines (i.e. whole blood, platelet concentrates, plasma, and ocular tissues, among others). The protocol for developing and evaluating the performance of temperature control systems is effective and can be adjusted to meet initial development criteria.

The temperature control systems that have been developed address the complex cold chain issues and are instrumental in maintaining the quality and safety of the biological products of human origin distributed by Héma-Québec.

Modernization of the monocyte monolayer assay

The monocyte monolayer assay (MMA) is a technique that helps guide decision making in complex blood compatibility cases, such as a recipient who has antibodies against antigens of blood groups because of previous exposure to blood products. The possibility of modernizing this test was recently raised, leading to this project.

On the one hand, an alternative test to the MMA, the monocyte suspension assay, was developed and made functional, and its performance was documented. The availability of post-transfusion clinical data will be a major upcoming issue, allowing a robust comparison of the performance of these two tests. On the other hand, avenues for modernizing and improving the MMA have been identified and are currently being used.

The conclusions of these studies were transferred to the Direction des laboratoires de référence to optimize their service offering.

Detection of antiplatelet antibodies by flow cytometry

The monoclonal antibody-specific immobilization of platelet antigens (MAIPA) is a test for identifying plateletspecific antibodies (anti-HPA). The discovery of specific anti-HPA antibodies enable the diagnosis of certain platelet-associated medical conditions, thereby ensuring that a patient receives proper care and has an adequate transfusion plan (when required). The MAIPA test has been used for several years at Héma-Québec's Reference Laboratories, but sometimes presents technical difficulties.

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Monocytes having internalized red blood cells

An alternative test to the monocyte monolayer assay, a technique that informs decisions for complex cases of blood compatibility, was developed.

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The aim of this project was to assess an alternative technique to the MAIPA. Unlike the standard MAIPA, the new technique (called "beads-MAIPA") is performed by flow cytometry and more closely resembles an enzyme-linked immunosorbent assay (ELISA). The beads-MAIPA has demonstrated a performance comparable to or better than that of the original MAIPA protocol. Among other things, this test proved adequate for detecting antiplatelet antibodies against the HPA-1, HPA-5 and HPA-15 systems. The technique could be performed during a single shift or over two days, providing operational flexibility.

Following a technological transfer and validation, the beads-MAIPA could be implemented in operations. The results of this assessment were transferred to the Reference Laboratories, which is responsible for researching and identifying antiplatelet antibodies.



The chemokine receptor CCR5 is expressed on human cells and provides an entry door for the human immunodeficiency virus (HIV). Mutations in this receptor eliminate its expression on the surface of cells, which prevents HIV from entering and infecting the cells. Two patients were cured of HIV thanks to an unrelated hematopoietic stem cell (HSC) transplant with a mutation in the CCR5 gene. HSC carriers of a mutation in CCR5 could thus become the subject of increased interest.

With this possibility in mind, a method for detecting CCR5 on the surface of cells was developed. The method uses flow cytometry to identify all cells that have a decreased (or absent) expression of CCR5. Unlike current methods that only detect some specific variants, this makes it possible to identify all the cells with a reduced expression of CCR5.

The method that has been developed will be used to identify units of cord blood cells that carry CCR5 mutations among those that are banked at Héma-Québec. Upon completion, this project could make available stem cells that carry a mutation abolishing the expression of CCR5. Such products could benefit patients with HIV.

Other contribution to innovation

potential of these cells.

Stem cells carrying a mutation that eliminates the cell-surface expression of the CCR5 receptor might benefit patients with HIV.

Health of Québec's population

Innovation

Product safety and efficacy, and donor safety

Support to operations

dissemination

Expression of the CCR5 receptor on the surface of donor stem cells

• The extraction of bone marrow from a living donor is a relatively invasive procedure performed only in specific circumstances. Héma-Québec has assessed the possibility of extracting stem cells from cadaveric, vertebral bone marrow. Preliminary results indicate that it is possible to obtain a large quantity of viable cells from such donations. Greater characterization will be needed to establish the

PRODUCT SAFETY AND EFFICACY, AND DONOR SAFETY

"The aim of research is to help, facilitate, optimize and find solutions to understand and solve life's big and small challenges. Participating in this mission is what motivates me every day. I am proud that my work can have a positive impact for donors and recipients."

Josée Perreault, PhD

Research Professional





Héma-Québec continuously deploys resources to ensure that Québecers benefit from safe and effective blood products. Our organization also sees to it that donors receive the best care before, during and after their donation.

Assessment of the quality of red blood cells from teenage donors and senior donors: A BEST study

Teenage blood donors and senior donors present an increased risk of iron deficiency and anemia. These donors are often underrepresented in studies that evaluate the effect of the donor on the efficacy of red blood cell transfusion.

The aim of this multicentre study, conducted in collaboration with the **Biomedical Excellence for Safer** Transfusion (BEST) was to assess the quality of the red blood cells from donors in these age groups. The study characterized 150 red blood cell units from 75 teenage donors and 75 senior donors. Relative to the red blood cells of the older donors, those of the teenage donors were smaller, had a higher volume and concentration of red blood cells and an increased cytoplasmic viscosity, and were more sensitive to oxidative hemolysis. According to the assessments of the immunomodulatory potential of the red blood cells, age did not seem to be associated with an altered expression of inflammatory markers.

In conclusion, the differences observed in this study are probably intrinsic to the red blood cells and reflect changes in the biology of the red blood cells over lifetime. The clinical effects of these changes remain unknown. The results of this study were published in the journal *Transfusion*; the article was the subject of a comment.

Variant Creutzfeldt-Jakob disease: a literature review on the risks of transmission through transfusion



Variant Creutzfeldt-Jakob disease (vCJD) can be transmitted through blood transfusion or the infusion of plasma-derived products. Published reviews on this subject, however, are outdated, concentrated on a single country or single type of product, or have not comprehensively synthesized the data from modelling studies.

Héma-Québec examined existing data on the observed and modelled risks of acquiring vCJD through transfusion. To date, five patients are suspected of having acquired vCJD following a blood transfusion. These patients all received a non-leukoreduced blood product in the United Kingdom between 1994 and 1999 before the adoption of universal leukoreduction in 1999. In descriptive cohort studies, no clinical case of vCJD were observed over approximately 13 years. In modelling studies, the risk of collecting a contaminated donation was generally lower than one in 23 million donations.

Innovation

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Training and knowledge dissemination

THE JOURNAL OF AABB

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Thrombocytopenia in traumatic brain iniury

Quality of RBCs from donors at the extremes education updates

Relative to the red blood cells of the older donors, those of the teenage donors were smaller, had a higher volume and concentration of red blood cells and an increased cytoplasmic viscosity, and were more sensitive to oxidative hemolysis.

Cover page of the journal Transfusion devoted to a study of the Biomedical **Excellence for Safer** Transfusion (BEST) in which Héma-Québec

participated.

Outreach

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The results did not show any association between an abnormal blood pressure reading and the risk of a vasovagal reaction or cardiovascular complication.

This very low risk, combined with the absence of transfusion cases over the past 20 years, suggests that vCJD presents a minimal risk to transfusion safety. The current trend toward re-assessing or, in certain countries, completely removing the donor criteria associated with vCJD seems justified and safe and could significantly broaden accessibility to donation. The results of this study were published in the journal Transfusion Medicine Reviews.

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Risks associated with variant Creutzfeldt-Jakob disease in a simulated cohort of Canadian blood donors

In over 20 years, no cases of variant Creutzfeldt-Jakob disease (vCJD) have been suspected of being transmitted by blood transfusion. Nevertheless, many countries maintain deferral criteria for blood donors related to this disease.

In collaboration with <u>Canadian Blood Services</u> (CBS), Héma-Québec developed a risk simulation model to assess the relevance of these deferral criteria in Canada. The model was based on a Monte Carlo simulation estimating the risk of collecting a blood donation contaminated with vCJD within a (simulated) cohort of 10 million donors who were followed to age 85. The model, which assumed that the current deferral criteria for vCJD were lifted, took into consideration numerous parameters: the prevalence of vCJD, the travel history of the donors, the genotype at codon 129 of the PRNP gene, donor demographics, and the type of labile blood product collected. In the most pessimistic scenario, it was estimated that at least 335 years may need to pass before one contaminated donation would be found in Héma-Québec's inventory. At CBS, it may take at least 20 years.

In conclusion, this model indicates that vCJD presents minimal risks for the blood supply in Canada. Based on this model, Héma-Québec was able to remove the deferral criteria related to vCJD, without impacting the safety of transfusion, while significantly expanding the pool of potential donors. The results of this study were published in the journal Vox Sanguinis.



Prior to the COVID-19 pandemic, individuals with abnormally high or low blood pressure readings were ineligible to donate blood. This criterion aimed to prevent adverse reactions, although little data justified this practice. At the start of the pandemic, Héma-Québec temporarily stopped measuring the blood pressure of donors because of the health situation, and no increase in adverse reactions occurred. This observation called into question the relevance of measuring donors' blood pressure.

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Measuring blood pressure before donation: Effects of an interruption during the COVID-19 pandemic

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Therefore, a study was conducted to determine if an abnormal blood pressure before a blood donation is associated with an increased risk of vasovagal reaction or cardiovascular complication. To this end, the measure of pre-donation blood pressure was reinstated for 12 months, without deferring donors with abnormal readings. The results did not show any association between an abnormal blood pressure reading and the risk of a vasovagal reaction or cardiovascular complication. Additional analyses (e.g. stratification by sex, age) will be conducted in the coming months.

In light of these results, the recommendation may be to stop measuring pre-donation blood pressure. Likewise, current risk mitigation strategies — i.e. hydration with 500 ml of water accompanied by a salty snack in the 30 minutes preceding the donation — could be strengthened, since these measures are effective in preventing vasovagal reactions.

Risk factors for T-cell lymphopenia in frequent platelet donors

Some people who frequently donate apheresis platelets (i.e. more than 20 donations a year over several years) present T-cell counts below the minimum reference threshold. This lymphopenia does not, however, affect the immune health of donors, as shown in a previous study by Héma-Québec. This anomaly may be caused by the retention of lymphocytes in the leukoreduction cone present on some apheresis collection devices.

An international multicentre study by the <u>Biomedical Excellence for Safer Transfusion</u> (BEST), in which Héma-Québec took part, evaluated the T-cell counts of donors whose platelets had been collected using an apheresis device fitted with — or lacking — a leukocyte reduction system cone. Lymphopenia was observed primarily in persons who donated frequently (i.e. more than 200 donations in their lifetime). However, donors whose platelets had been collected using a device fitted with a leukoreduction cone had a higher risk of lymphopenia. Among these donors, none showed lymphopenia when the cone was rinsed to return the cells to the donors at the end of the donation, whereas 14% presented with lymphopenia without this rinseback procedure.

In this study, lymphopenia associated with apheresis platelet donations was more frequent following donations made using devices fitted with a leukoreduction cone. Rinsing the cone at the end of a donation could dislodge the T-cells from it and thereby mitigate lymphopenia. The data from this study were published in the journal <u>Transfusion</u> and commented on in an <u>editorial</u> in the same journal.

Support to operations

Training and knowledge dissemination

Rinsing the leukoreduction cone at the end of a donation could dislodge the T-cells from it and thereby mitigate the lymphopenia experienced by some donors.

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Serious adverse events related to stem cell transplantation during the COVID-19 pandemic During the COVID-19 pandemic, the stakeholders involved in hematopoietic stem cell (HSC) transplantation (i.e. registries, collection centres and transplant programs) implemented numerous changes aimed at protecting donors and ensuring that recipients had access to compatible, quality HSCs. Despite these efforts, the pandemic may have caused adverse effects related to an HSC donation or transplant.

A study was conducted by members of the committee of the <u>World Marrow Donor Association</u> (WMDA) tasked with analyzing serious product events and adverse reactions (SPEARs) associated with HSC transplants; to this end, the committee relied on the participation of an executive from Héma-Québec. The aim was to assess the incidence of adverse effects associated with COVID-19 in 2020. A total of 74 SPEARs were reviewed and classified as being linked to the donor (n = 41; 55%), the recipient (n = 3; 4%), technical problems (n = 31; 42%), or transportation problems (n = 4; 5%). The event reported most frequently was cells remaining unused, often because of technical problems that compromised cell survival or dissociation of the donation and transplant (stemming from cryopreservation). The lessons learned include the importance of confirming the eligibility of the recipient before mobilizing or collecting HSCs and minimizing the time between the collection of the cells and the transplant. Transplant centres must also familiarize themselves with anticipated cell losses when stem cell products from peripheral blood or bone marrow are cryopreserved. Centres must also have validated the viability tests for quality assurance. Reassuringly, no donors seem to have fallen severely ill due to granulocyte-colony-stimulating factor, and no cases of SARS-CoV-2 transmission to a recipient have been reported. Only one transport failure of a donation was reported.

This analysis suggests that the pandemic had a limited effect on the donation and transplantation of hematopoietic stem cells. The data from this study were published in the journal <u>Transplantation and Cellular Therapy</u>.

Characterization of stem cells mobilized by AMD3100

For several years, apheresis has been the preferred approach for collecting hematopoietic stem cells (HSC), since this procedure is less invasive than collecting them from the bone marrow. The procedure requires the administration of an agent — typically granulocyte-colony-stimulating factor (G-CSF) — to mobilize HSCs in the bone marrow toward the bloodstream. However, this G-CSF-mediated mobilization can prove ineffective for certain donors, and for patients who might benefit from autologous transplants, with or without gene therapy.

The AMD3100 molecule (Mozobil[®]) is another HSC mobilization agent that has been approved by the Food and Drug Administration for a dozen years. AMD3100 is less effective when used alone (without G-CSF), but doing so significantly simplifies the clinical protocol: a single injection of AMD3100 is required on the eve of the collection, compared with one daily injection over the 4 to 5 days preceding the collection with G-CSF.

Given this advantage, Héma-Québec characterized the similarities and differences of HSCs mobilized by G-CSF and AMD3100. The preliminary results show that the properties of the HSCs mobilized by AMD3100 appear to slightly differ when the HSCs are cultured in vitro. A characterization of a greater number of donations will be needed to determine the potential impact of using AMD3100.

Product safety and efficacy, and donor safety

Support to operations

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Maryska, who signed up to the stem cell donor Registry

A study suggested that the COVID-19 pandemic has had a limited impact on the activities related to the donation and transplantation of hematopoietic stem cells.

Outreach

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LOOKING INTO THE FUTURE Héma-Québec | 2023 Scientific Activities Report





A literature review revealed that HIV infections rarely occur while on pre-exposure prophylaxis.



Pre-exposure prophylaxis (PrEP) is a preventative strategy that reduces the risk of transmission of human immunodeficiency virus (HIV). New low-toxicity, long-acting PrEP formulations are improving adherence to prophylaxis and preventative efficacy. However, PrEP is not 100% effective in preventing the transmission of HIV infections, especially because of suboptimal adherence and antiviral-resistant strains. In addition, an HIV infection contracted while on PrEP could go undetected by current tests, which would increase the risk of transmission through transfusion. This possibility has raised concerns in the blood transfusion community but has not been well documented.

To fill this gap in data, Héma-Québec surveyed the state of knowledge on the risk of contracting HIV while on PrEP, focusing on the risk of introducing HIV into the blood product inventory. This review revealed that HIV infections while on PrEP are rare. In addition, viremia and antibody levels can remain undetectable or at the limit of detection long after stopping PrEP, especially with long-acting formulations.

In light of these data, current recommendations to defer donors for at least three months after the last dose of oral PrEP, or two years after the last dose of long-acting PrEP, seem justified since such deferrals maintain transfusion safety. This literature review was published in *Transfusion Medicine Reviews*.



Relevance of measuring hemoglobin in apheresis plasma donors: A retrospective cohort study

During plasma donations, the apheresis procedure returns most of the red blood cells to the donor; the resulting loss of red blood cells is, therefore, minimal. Thus, systematically measuring hemoglobin levels before plasma donations might be overly cautious.

To test this hypothesis, Héma-Québec evaluated the association between the frequency of apheresis plasma donations and the hemoglobin levels of donors. The study comprised 9,535 men and 9,409 women who had made between 2 and 16 apheresis plasma donations. The men maintained hemoglobin levels well above the deferral threshold, and their hemoglobin levels dropped by only 0.17 g/dL between the 2^{nd} and 16^{th} donation (p < 0.0001). The women also maintained hemoglobin levels above the deferral threshold, and their hemoglobin levels decreased by 0.08 g/dL between the 2nd and 16th donation.

In conclusion, the frequency of apheresis plasma donations was not associated with clinically significant changes in hemoglobin levels. These data question the relevance of measuring hemoglobin levels at every apheresis plasma donation, at the very least for frequencies of less than seven to eight donations per year. This study was published in the journal Vox Sanguinis.

The donor health questionnaire, which is completed by each donor before a donation, contains questions on PrEP use for HIV prophylaxis

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Pre- and post- exposure prophylaxis for HIV: risk of transmission by transfusion and change to the selection criteria by blood services



Criteria for launching an investigation into a possible septic transfusion reaction: A literature review

Septic transfusion reactions (STR) can occur following the transfusion of a blood product contaminated with bacteria, causing septicemia.

Héma-Québec carried out a literature review to explore and map the literature on the criteria for launching an investigation when an STR is suspected. Four electronic databases and the grey literature were queried. Most of the references reported a single set of criteria, and only two reported four or more sets of criteria. In total, almost 60 different sets of criteria were identified.

In conclusion, this literature review revealed a significant variation in the criteria used to investigate suspected STRs. Other studies are needed to improve the diagnostic precision of the criteria for launching an inquiry into a suspected STR. These results were published in the journal Vox Sanguinis.



Warming of cryopreserved hematopoietic stem cell products

This project was a follow-up to a study conducted in 2021 on the characterization of the warming of cord blood within the normal framework of operations.

The aim was to characterize the thermal properties of cord blood subjected to extreme warming events and to compare the various freezing devices (cryovials and bags). According to the results, the rapid test that measures the functionality of stem cells from cord blood (the IL-3-pSTAT5 test developed by Héma-Québec) was just as sensitive as the reference test based on colony-forming units, which is much more time-consuming. This study also established a theoretical threshold of 129 °C not to be exceeded when warming, thanks to an advanced calorimetry technique.

Ultimately, this project showed the relevance of the IL-3-pSTAT5 test to Héma-Québec's Cord Blood Bank operations in following up and effectively evaluating the quality of the Bank's products.



Deformability of red blood cells from donors with iron deficiency: A longitudinal follow-up during the storage period

The deformability of red blood cells reflects their ability to circulate in blood vessels following a transfusion. However, this property is not well characterized for the red blood cells of non-anemic donors with iron deficiency who are eligible to donate blood.

The objective of this project was to compare the deformability of red blood cells in donors with low or normal ferritin levels. Donors were divided into three groups according to their ferritin levels measured at the time of donation. The deformability of the red blood cells was then measured at the start (day 1) and end (day 42) of the storage period. Despite the small sample size, the

The concentration of ferritin measured at the time of donation correlated with the evolution of the deformability of the red blood cells during storage.

Outreach

Research partners

Funding

Research organizational structure et Héma-Québec

Measure of red blood cell deformability



concentration of ferritin measured at the time of donation correlated with the evolution of the deformability of the red blood cells during storage.

The continuation of the project will aim at using a larger sample size, along with a greater diversity of donors (e.g. based on sex and ethnicity). The project will include a component on oxidative stress reduction in donors presenting with a low ferritin level at the time of donation.

Efficacy of the disinfection of cardiovascular tissues with antibiotic cocktails at 37 °C

Heart valves collected from deceased donors are often contaminated with microorganisms considered unacceptable for eventual transplantation. While the valves are disinfected before being put into inventory, a significant number are rejected because the disinfection process does not sterilize the tissues in their entirety.

This project reviewed the preparation of the valves to avoid the contaminations that often occur at this stage. Rinsing the hearts before collecting the valves proved highly effective in reducing contamination.

This study led to the development of a heart rinsing protocol that was implemented in the human tissue Bank's operations. The number of contaminated valves significantly decreased after implementation of this protocol, thus improving the availability of this tissue for patients in need.

Interference of daratumumab in serological tests

Daratumumab is an anti-CD38 antibody used to treat multiple myeloma. This medicine interferes with the detection of anti-erythrocyte antibodies (since red blood cells weakly express CD38) and is therefore a transfusion safety issue.

Two approaches were explored to counter this interference. The first used synthetic peptides capable of neutralizing daratumumab; this approach was found to be inconclusive. The second was based on the adsorption of daratumumab onto cell membranes expressing CD38. While effective, this approach presents the inconvenience of reducing the strength of the reaction of some alloantibodies, thereby running the risk of making them undetectable.

The use of recombinant CD38 as a way of adsorbing daratumumab will be considered as part of a new project that will include a component on the neutralization of therapeutic anti-CD47 (e.g. magrolimab, lemzoparlimab) — which are new therapeutic antibodies that also interfere with red-cell serology tests.

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The number of contaminated valves significantly decreased after the implementation of a disinfection protocol that uses antibiotic cocktails.

Treatment of a cardiovascular tissue

Outreach

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SUPPORT TO OPERATIONS

"I'm proud to be part of Héma-Québec's mission by helping to provide high-quality blood products to the population. The Medical Affairs and Innovation team is a group of scientists whose role is to provide expertise and support to the operations. Challenges are my greatest source of motivation."

Marie-Josée Fournier, MSc

Research Professional





Héma-Québec also conducts several scientific activities linked to its operations.



Efficacy of various techniques for cleaning breast pumps to reduce microbial loads

Milk from a mothers' milk bank is a nutritional source recommended for premature babies whose mothers cannot breastfeed. Several disinfection techniques for breast pumps exist to reduce the risk of contamination of the milk at the time of donation. The comparative efficacy of these techniques is, however, not well documented.

The aim of this study was to evaluate the efficacy of various methods of cleaning and disinfecting breast pumps to recommend one to donors of mother's milk. Three models of breast pumps were used with contaminated milk. Two device rinsing techniques (i.e. in cold water or hot soapy water) and two device disinfection techniques (i.e. in the microwave using a system designed for this use, or in boiling water) were tested. In the end, rinsing in hot soapy water and disinfecting in boiling water proved to be the most effective methods; the use of the microwave was the least effective disinfection technique of all those tested.

Cleaning breast pumps in hot soapy water followed by a 10-minute disinfection in boiling water is the current method recommended to donors of Héma-Québec's mother's milk Bank to minimize the risk of contamination of the banked milk intended for premature babies. The data from this study were published in the journal *Breastfeeding Medicine*.

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Technical and operational assessment of a new serum protein analyzer

The serum proteins of plasma donors must be monitored to ensure that repeated donations do not impact their health. These tests are currently performed by the Product Qualification Laboratory using a device acquired in 2009, combined with a refractometer. Maintenance and repairs for this device will soon no longer be supported by the manufacturer. Therefore, Héma-Québec intends to acquire a new serum protein analyzer to replace it.

The goal of this project was to establish the analytical performance of Binding Site's Optilite® analyzer in measuring immunoglobulin G (IgG) and total proteins; a technical and operational assessment was also carried out. Prior to an operational assessment, the technical characteristics of the device were first analyzed and evaluated to ensure that it meets the minimal required criteria. The device's limits were evaluated: precision, accuracy, dynamic range, contamination risk, hemoglobin-induced interference, speed, and stability of reagents and analyzed samples.

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This evaluation confirmed the operational performance of the Optilite analyzer. A new deferral threshold based on the IgG concentrations had to be established, without compromising the health and safety of donors.

, Transportation study of ocular tissues in the KODIAKOOLER® shipping box

At extreme winter temperatures (i.e. 30 °C), the three formats of boxes used by Héma-Québec proved to be inadequate for transporting ocular tissues. Our organization needed, therefore, to optimize the process for transporting ocular tissues under these conditions.

The aim of this project was to develop a transportation solution that prolonged the packaging and transportation time of ocular tissues. The proposed solution required phase change materials that were pre-conditioned and positioned optimally in one of the box formats already in use. To validate the transportation process, this new temperature control system was exposed to winter conditions. In the end, a single-use box was developed that maintains the internal temperature of the ocular tissues between 1 °C and 10 °C for 19 hours, irrespective of the outdoor temperatures observed in Québec.

Three reports were issued, and one study was supervised by the Direction de l'assurance qualité. The shipping box was successfully validated in August and has been in use since October 30, 2023.

A screen to identify donors with IgA deficiency

Immunoglobulin A (IgA) deficiency is a relatively frequent hematological condition. Certain individuals with this deficiency produce anti-IgAs, which can cause a severe allergic reaction if transfused with a product containing a normal concentration of IgAs. This adverse reaction can be prevented by transfusing IgA-deficient blood products.

Héma-Québec maintains a registry of donors with IgA deficiency to supply adequate blood products to recipients with the same condition. Mass screening has been conducted at regular intervals since 2002. In 2023, Héma-Québec screened (by fluorimetry) donors from A and AB blood groups to identify those who were IgA-deficient. IgA-deficient donations were then confirmed by a quantitative IgA analysis conducted externally. The donors with confirmed IgA deficiency will be added to the registry of donors with this condition. This will allow Héma-Québec to maintain its reserve of IgA-deficient products.

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Héma-Québec maintains a registry of donors with immunoglobulin A deficiency to supply adequate blood products to recipients with the same condition.

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New anti-IgA screening test

Since 2013, Héma-Québec has been providing an IgA dosing service for patients referred by hospitals.

To improve its service offering and to better identify patients at risk of allergic transfusion reactions, our organization has developed an anti-IgA screening test by cytometry. The test is performed using beads covered with IgAs which bind anti-IgAs. Their presence is then detected by flow cytometry. During the past year, this procedure was tested to establish all acceptance criteria. The test was then validated by using it to identify samples whose anti-IgA status was unknown to the user (i.e. blindly), thereby making it possible to approve the use of this test for analyses in research mode.

Since April 2023, this new test has been part of the analytical services offered to hospitals. It is currently being used to detect anti-IgAs in IgA-deficient patients.

Implementation of pathogen inactivation technology and elimination of the deferral criteria related to sexual behaviour: modelling of possible impacts

Pathogen inactivation technology (PIT) reduces the risk of transmission of infections through transfusion and could eventually ease — or even eliminate — certain deferral criteria to blood donation. Given the significant advantages offered by this technology, Héma-Québec plans to introduce PIT in the coming years. This change will have major repercussions on all Héma-Québec's activities and must, therefore, be prepared and validated with care.

To fully understand the potential benefits of PIT, Héma-Québec has developed a model that estimates the residual risk of transmission of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) in Canada — following the implementation of PIT and without deferrals linked to the donors' sexual behaviour. In the most probable scenarios being considered, and assuming the removal of the deferral criteria with the implementation of PIT, the risks of transmission of HIV, HBV, and HCV were all lower than the current risk.

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This modelling analysis suggests that PIT significantly reduces the residual risk of transmission of HIV, HBV, and HCV through transfusion and could allow for the removal of donation deferral criteria related to sexual behaviour. Héma-Québec is currently conducting a project to establish the parameters for collecting and preparing products with PIT and to better understand the impacts on our processes.

Other projects supporting operations

- Héma-Québec assessed the possibility of using a halocarbon solution as a thermal temporization medium for the sensors of freezers maintained at -80 °C; this should minimize the rapid temperature variations caused by door openings.
- The humidity level used during the colony-forming assay for hematopoietic stem cells (HSC) was tested and optimized.
- In a second study dealing with the same assay, the wait time before culturing HSCs was shown not to be critical; the colony-forming assay can thus be performed at the same time as the HSC count (rather than sequentially).
- In another project, adding one or two centrifugation steps (which is sometimes necessary to improve blood separation) had no impact on the quality of frozen rare blood.
- The effect of withdrawing the volume of residual air from the bags of apheresis plasma was assessed; the study highlighted certain operational issues that will need to be considered in the event that this step is abolished.
- Given the possible arrival of new quality control stem cell tests, the size of the segments of cord blood units (meeting regulatory standards) was studied.
- Our organization also assessed the potential effect of an eventual change of auto-lancing device on the deferral rate of donors. Hemoglobin levels measured with the new auto-lancing device were associated with a deferral rate equal to that observed with the current model.

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Since its founding, Héma-Québec has contributed to training the future generation of specialists in basic and applied research in fields that are relevant to its activities. Our organization also regularly welcomes physicians wishing to specialize in transfusion medicine. Beyond this specialized training, Héma-Québec offers interns at the college and university levels the opportunity to acquire practical experience to meet the requirements of their study program.

During 2023, the scientific staff of the Vice-présidence aux affaires médicales et à l'innovation (VP-AMI) co-directed the work of six master's or doctoral students. During the same period, three researchers pursued a postdoctoral internship at the VP-AMI, and four undergraduate Université Laval students completed an internship in our Québec City laboratories in 2023. Finally, the Vice-présidence à la médecine transfusionnelle (VP-MT) welcomed two fellows who took part in training internships in transfusion medicine.

Training in the life sciences

Persons with a university degree in the life sciences can pursue graduate studies at Héma-Québec, while benefiting from guidance by a supervisor in a university setting. These students sometimes receive grants from funding agencies, in particular Mitacs, the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institutes of Health Research (CIHR), the Fonds de recherche du Québec - Santé (FRQS), and the Fonds de recherche du Québec - Nature et technologies (FRQNT), based on the excellence of their academic record.

The students are supervised by scientists with a variety of backgrounds who are specialists in microbiology, cell biology, molecular biology, genetics, bioinformatics, public health, epidemiology, mathematics or statistics. This interdisciplinarity provides the students with a rewarding learning experience.

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The various stages of their academic career are summarized at the right.

The quality of their work contributes to Héma-Québec's basic mission and innovation objectives. In 2023, a PhD student who conducted her thesis work at Héma-Québec, Yelena Boccacci, distinguished herself by earning a special mention on the Dean's Honour Roll of Université Laval's Faculty of Medicine.

Training of fellows at Héma-Québec

Héma-Québec's fellows are physicians specializing in hematology, pathology or anesthesia who undertake one to two years of advanced specialized training in transfusion medicine. They receive a grant for completing their training and super-specialization. The various stages of specialized and advanced specialized training are outlined on the right.

Currently, three advanced specialization programs are accredited by the Royal College of Physicians and Surgeons of Canada (RCPSC): those of the University of Toronto (Toronto), McMaster University (Hamilton), and the University of British Columbia (Vancouver). Since none of these universities is in Québec, fellows must complete their training at one of the universities listed above. As part of their training, the fellows must complete an internship of at least four months at a blood center. Those who receive a scholarship in Québec complete their internship at Héma-Québec instead of Canadian Blood Services.

During their internship at Héma-Québec, fellows spend two months at the Montréal facility where they are exposed to the operational activities of our various product lines, donor recruitment activities, our quality management system, and the services provided by the Reference Laboratories, the Product Qualification Laboratory and the Stem Cell Donor Registry. They also spend two months at the Québec City facility, where they focus on studying complex cases analyzed by the Québec City Reference Laboratory and the Research Department. They also have an opportunity to exchange ideas with the Human Tissues Operations teams and Research teams. The fellows have specific training objectives to achieve and regularly work with members of Héma-Québec's staff to answer important and specific questions. They are also very involved in research and take part in several projects in collaboration with Héma-Québec.

Organization of activities and preparation of resources for patients and their families

In addition to training the next generation of scientists, Héma-Québec's scientific staff contributes to developing training sessions and workshops and preparing resources for patients and their family. In addition to training many professionals and students, their initiatives have fostered the dissemination of knowledge to the public and within the scientific community.

Innovation

Product safety and efficacy, and donor safety

Support to operations

dissemination





Knowledge dissemination

Héma-Québec is proud of its association with the Science Pop Competition, whose provincial final was held on Mary 28, 2023. This Québec-wide initiative, which was organized by the Montreal Clinical Research Institute (IRCM) with the support of the Fonds de recherche du Québec — Santé, showcases the scientific popularization talents of student-researchers, in addition to providing a window on the outstanding research being conducted in Québec. Héma-Québec enthusiastically offered two internships to the winners of the provincial final of this competition.

During 2023, Héma-Québec also organized two virtual symposia. The first, which was held on April 20, 2023 and was organized by Héma-Québec and Canadian Blood Services (CBS), dealt with strategies in place in various countries to reduce the risk of infections transmitted through transfusion amid the removal of the deferral criteria for blood donation based on sexual orientation. The second, which was held on September 22, 2023 and was organized jointly by Héma-Québec and the Réseau de thérapie cellulaire, tissulaire et génique du Québec (ThéCell), dealt with the opportunities and challenges related to advances in cell therapy and regenerative medicine. These two events, which brought together international and local experts, shed light on several challenges for our organization.

Training of professionals and students

Héma-Québec also contributes to maintaining the highest quality standards by producing educational material intended for our partners in hospitals. For several years, the organization has offered training in red blood cell immunology intended for laboratory technicians working in hospital blood banks in Québec (theoretical and practical training) and across the world (through the educational Web platform). The training, offered in three languages (French, English and Spanish), is aimed at acquiring a methodology and techniques to solve immunological problems encountered daily in a blood bank laboratory and during serological studies of persons with autoimmune hemolytic anemia (click <u>here</u> for more details). This training had 179 registrations in 2023.

Héma-Québec also offers regulatory training aimed at ensuring that the collection specialists working in partner hospitals are properly trained and qualified to collect cord blood. In the past year, there were 83 registrations for this training.

Héma-Québec's researchers and physicians also give university courses to scientists in training. Some teach sessions of the molecular medicine and immunology course, which is offered to master's and doctoral students, and to postdoctoral interns in the neurosciences, molecular medicine, microbiology-immunology, and pharmaceutical sciences. Other researchers participate in a course dealing with stem cell transplantation. Physicians working in our organization also offer training in sickle cell anemia, neonatal anemia and apheresis. An expert in statistics and epidemiology also teaches a course on biostatistics.

Finally, a member of the scientific staff contributed to developing an educational platform to standardize the training of resident physicians in hematology.

Héma-Québec's researchers and physicians also give university courses to scientists in training.

Health of Québec's population

Innovation

Product safety and efficacy, and donor safety

Support to operations Training and knowledge dissemination

Outreach

Research partners

Funding



Reference documents

As previously described, Héma-Québec took part in drafting the first edition of an immunohematology guide intended for staff working in a blood bank laboratory. This work will guide medical technologists so that they can exercise their professional judgment while rigorously applying established policies and procedures.

In collaboration with the <u>Centre hospitalier universitaire Sainte-Justine</u> (CHU Sainte-Justine) and the Centre hospitalier universitaire de Sherbrooke (CHUS), Héma-Québec also contributed to updating the recommendations for the use of phenotyped blood. These recommendations will help improve the quality of care provided to patients with blood disorders, such as hemoglobinopathies and hemolytic anemia.

Our organization also participated in updating a guide published by the ministère de la Santé et des Services sociaux that is intended for families of children with sickle cell anemia. This guide provides families with information on the disorder and the optimal care that can be provided.

Héma-Québec's scientific staff also took part in updating the Guide for declaring adverse events associated with the transfusion of blood products. The objective of this guide is to facilitate the analysis of errors or adverse events that may arise in health institutions as part of the Québec hemovigilance system.

Furthermore, the Vice President, Transfusion Medicine, co-chaired a joint committee of the National Advisory Committee (NAC) and the National Advisory Committee on Blood and Blood Products (CCNMT), whose mandate was to develop new recommendations regarding the use of irradiated blood products in Canada. These recommendations are based on a review of current practices, guidelines and recent literature on the indications for irradiated products and the quality of irradiated red blood cells.

Finally, Héma-Québec took part in updating recommendations for accurately determining the RhD blood group of recipients and thereby standardizing practices in hospitals. These recommendations should prevent discrepancies in the RhD blood group of a recipient and minimize the risk of alloimmunization, without overusing RhD-negative blood products.

Héma-Québec's scientific staff participates in the development of guidelines.

Training and knowledge

Outreach

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OUTREACH

PUBLICATIONS

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Outreach

Research partners

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Outreach

Funding



INTERNAL REPORTS

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 Cayer, M. P., Fonseca, S., Brouard, D., de Grandmont, M. J. Observations de décantation du sang total lors des filtrations avec les dispositifs de prélèvements Leukotrap WB system (T1/T6) (AMI-2139/33622). Report presented to the Vice-présidence aux produits sanguins et au lait maternel, August 25, 2023.

3. Cayer, M. P., Fonseca, S., Robidoux, J., Laforce-Lavoie, A., Dussault, N., de Grandmont, M. J., Brouard, D. Évaluation de performances du dispositif Leukotrap WB system – 500 mL distribué par Haemonetics. Rapport 2 de 2: qualité des produits sanguins préparés à partir de dons de sang total prélevés avec le dispositif T6 (AMI-2139/33622). Report presented to the Vice-présidence à la qualité et au développement and the Vice-présidence aux produits sanguins et au lait maternel, August 31, 2023.

4. Cayer, M.P., Lampron, M.C., de Grandmont, M.J., Robidoux, J., Brouard, D. Vérification de l'équivalence des dispositifs de mélange plaquettaire Reveos (AMI-2230/33720). Rapport présenté à la Vice-présidence à la qualité et au développement — Direction de l'assurance qualité, et à la Vice-présidence aux produits sanguins et au lait maternel le 15 novembre 2023.

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9. Dussault, N., Boyer, L., de Grandmont, M. J., Brouard, D. Suivi de température des PCM5 pendant un conditionnement en phase liquide en présence ou non de sacs Ziploc (AMI-2209/AP-01-02). Report presented to the Vice-présidence aux produits sanguins et au lait maternel et à la Vice-présidence à la qualité et au développement — Direction de l'assurance qualité, May 30, 2023.

10. Dussault, N., Boyer, L., de Grandmont, M. J. Étude de transport de tissus oculaires à température réfrigérée dans la boite Kodiakooler de volume moyen en conditions estivales d'exposition (ET-23-003-R). Report presented to the Vice-présidence aux affaires médicales et à l'innovation, June 2, 2023.

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Report presented to the Vice-présidence à la qualité et au développement and the Vice-présidence aux produits sanguins et au lait maternel, November 6, 2023.

12. Dussault, N., Boyer, L., Ducas, É., Cayer, M. P., de Grandmont, M. J., Brouard, D. Résumé des activités menant à l'identification du nouveau système thermorégulateur pour le transport de prélèvements de sang total faisant intervenir un traitement à froid (AMI-2209/AP-01-02). Report presented to the Vice-présidence à la qualité et au développement — Direction de l'assurance qualité, the Vice-présidence à la chaîne d'approvisionnement, and the Vice-présidence aux produits sanguins et au lait maternel, January 12, 2023.

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17. Dussault, N., de Grandmont, M. J., Brouard, D. Caractérisation du système thermorégulateur VIP PE-PCM5 et de ses composantes développées pour le transport du sang total (AMI-2209/AP-01-02). Report presented to the Vice-présidence à la chaîne d'approvisionnement, February 10, 2023.

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M. J., Brouard, D. Influence du format de glace utilisé avec
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(AMI-2305/33742). Report presented to the Vice-présidence
aux affaires médicales et à l'innovation — Direction de
l'exploitation des tissus humains, May 19, 2023.

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23. Laforce-Lavoie, A., Cayer, M. P., de Grandmont, M. J., Dussault, N., Nolin, M. È., Brouard, D. Évaluation de la méthode d'échantillonnage non destructrice de culots globulaires développée par la Société canadienne du sang pour des applications de contrôle qualité (GÉO-172/33307). Report presented to the Vice-présidence à la qualité et au développement, the Vice-présidence aux produits sanguins et au lait maternel, the Vice-présidence à la chaîne d'approvisionnement, and the Vice-présidence aux affaires médicales et à l'innovation, April 27, 2023. 24. Laforce-Lavoie, A., Cloutier, M. Étude sur l'impact de multiples centrifugations des culots globulaires avant la glycérolisation (AMI-2228/33721). Report presented to the Vice-présidence à la médecine transfusionnelle, September 27, 2023.

25. Laforce-Lavoie, A., Landry, P., Lewin, A., Cloutier, C. Évaluation de performance de l'analyseur de protéines sériques Optilite (AMI-2225/33301). Report presented to the Vice-présidence aux produits sanguins et au lait maternel and the Vice-présidence à la médecine transfusionnelle, June 13, 2023.

26. Laforce-Lavoie, A. Landry, P., Lewin, A., Cloutier, C. Détermination du nouveau seuil d'interdiction des donneurs de plasma selon le contenu en immunoglobines G (AMI-2225/33301). Report presented to the Vice-présidence aux produits sanguins et au lait maternel, the Vice-présidence à l'expérience clientèles et aux communications, the Vice-présidence à la chaine d'approvisionnement, and the Vice-présidence à la médecine transfusionnelle, November 8, 2023.

27. Laforce-Lavoie, A., Dussault, N., Cloutier, M. Étude sur l'impact d'une glycérolisation de culots globulaires T1 conservés jusqu'à 21 jours (AMI-2333/33851). Rapport présenté à la Vice-présidence à la médecine transfusionnelle le 15 décembre 2023.

28. Laforce-Lavoie, A., Deschênes, É, Cloutier, M. Établissement d'un protocole de congélation des hématies avec un dispositif modifié (AMI-2334/33860). Rapport présenté à la Vice-présidence à la médecine transfusionnelle et à la Vice-présidence à la qualité et au développement — Direction de l'assurance qualité le 22 décembre 2023.

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30. Perreault, J., Trépanier, P. Révision de la taille des segments contigus à la poche de sang de cordon - AMI-2314. Rapport présenté à la Vice-présidence à la médecine transfusionnelle le 13 novembre 2023.

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Training and knowledge dissemination

31. Plourde, K., Laganière, J. Évaluation d'un séquenceur troisième génération pour le génotypage des groupes sanguins (AMI-1909). Report presented to the Vice-présidence aux affaires médicales et à l'innovation, November 29, 2023.

32. Robidoux, J., de Grandmont, M. J. Projet pilote : évaluation de performances de l'autopiqueur SteriLance Flex 3 en contexte opérationnel au centre Globule Lebourgneuf (AMI-33840). Report presented to the Vice-présidence aux produits sanguins et au lait maternel – Qualité, conformité et projets opérationnels, October 20, 2023.

33. Tremblay, T., Loubaki, L. Rapport de fin de projet sur la mitigation de l'interférence du daratumumab dans les tests sérologiques (INNOV-33141). Report presented to the Vice-présidence à la médecine transfusionnelle — Direction des Laboratoires de référence, November 7, 2023.

34. Trépanier, P., Perreault, J. Détection d'anticorps antiplaquettaires par cytométrie en flux (AMI-2137). Report presented to the Vice-présidence à la médecine transfusionnelle, March 27, 2023.

35. Trépanier, P., Rhéaume, M. È. Impact de l'humidité sur l'épreuve de croissance des colonies des cellules souches (AMI-2308). Report presented to the Vice-présidence à la médecine transfusionnelle — Direction des cellules souches, March 7, 2023.

36. Trépanier, P., Rhéaume, M. È. Étude de faisabilité de la préparation de dérivés de sang de cordon (AMI-2004). Report presented to the Vice-présidence à la médecine transfusionnelle, October 5, 2023.

REFERENCE DOCUMENTS

Working group on the immunohematology guide. Immunohematology Guide. (2023). Page consulted on October 24, 2023. URL: <u>https://www.optmq.org/DATA/</u> <u>TEXTEDOC/GUIDE-D-IMMUNOHEMATOLOGIE-2023.pdf</u>.

Ministère de la Santé et des Services sociaux – Direction de la biovigilance et de la biologie médicale. Recommendations for Rh blood group determination (2023).

Outreach

Research partners

Funding



Ministère de la Santé et des Services sociaux - Direction de la biovigilance et de la biologie médicale. Use of phenotyped blood (2023).

National Advisory Committee on Blood and Blood Products. Recommendations for use of irradiated blood components in Canada: a NAC and CCNMT Collaborative Initiative (2023). Page consulted on November 3, 2023. URL : https://nacblood. ca/en/resource/recommendations-use-irradiated-bloodcomponents-canada.

DISSERTATIONS AND THESES

Boccacci, Y. Modélisation in vitro de variants génétiques dans des globules rouges dérivés de cellules souches hématopoïétiques avec CRISPR-Cas9. (2023). Doctoral thesis. Université Laval.

Dubois, C. Quantification des immunoglobulines A par résonance des plasmons de surface pour identifier les individus IgA-déficients. (2023). Master's dissertation. Université de Montréal.

COMMUNICATIONS PRESENTED AT CONVENTIONS, WORKSHOP FACILITATIONS

Annual Conference of the Association of Medical Microbiology and Infectious Disease (AMMI) Canada, Toronto, Canada, March 28–31, 2023

Oral presentations

Drews, S. J., Renaud, C. A possible transfusion transmitted case of malaria in Canada: What we know, what we don't know and what we wish we knew.

Gaussen, A., Renaud, C., Lewin, A., Delage, G. A surveillance system to monitor existing and emerging pathogens that could pose a threat to blood safety.

O'Brien, S., Lewin, A. Data linking SARS-CoV-2 data between Canadian Blood Services and public health databases.

Posters

Acharya, D., Gaussen, A., Poder, G. T., Lambert, G., Renaud, C., Nawej, K., Lewin, A. Criteria used in identifying septic transfusion reactions: A scoping review of available evidence.

Renaud, C., Domingo, M. C., Deschenes, J., Cortes, L., Lemay, A.S., Lewin, A. Septic transfusion reaction related to platelet contamination is rare but is still happening. Would you recognize it?

Annual Conference of the Canadian Society for Transfusion Medicine (CSTM), Montreal, Canada, May 25-28, 2023

Oral presentations

Drouin, M., Rochette, S., St-Louis, M., Lewin, A., Laganière, J. Prevalence of serological weak D phenotypes in the general population of Québec: A focus on weak D type 42.

Fonseca, S., Cayer, M. P., Matte, M., Brouard, D. Antibacterial coating, development, preparation and characterization methods.

Prokopchuk-Gauk, O., Robitaille, N., Devine, D., Laroche, V., Morrison, D., Musuka, C., Shih, A., Tinmouth, A. Revised NAC-CCNMT irradiation recommendations: Proposed updates and a summary of Canadian TA-GVHD hemovigilance data.

Workshops

Baillargeon, N. Case studies - result interpretation, what to do when serology & genotyping don't match.

Deschênes, J. "TRALI or not TRALI".

Leiva-Torres, G. A. Demystifying the RHCE genetics.

Posters

Dubois, C., Robidoux, J., Brouard, D. Towards a point-of-care method for the detection of ferritin in blood using a surface plasmon resonance (SPR) sensor.

Labrecque, M. M., Murru, A., Paré, G., Acker, J., Lessage, S., Bazin, R., Girard, M., Fernandes, M.J. Development of a storage solution for granulocyte concentrates used to treat lifethreatening infections.

Product safety and efficacy, and donor safety

Support to operations

Lampron, M. C., Tremblay-Desbiens, C., Loubaki, L. Assessment of the impact of cannabis use on the quality of blood products.

Pelletier, M.P., Girouard, A. M., Amesse, C., Robitaille, N., Rivard, G. E., Arsenault, A. First home blood transfusion in a pediatric patient in Québec.

Robidoux, J., Cayer, M. P., Dussault, N., de Grandmont, M. J., Brouard, D. Flex capacity — comparing performances of three platelet concentrate production processes to meet inventory targets in crisis situation.

Robidoux, J., Ceneston, N., Lebrun, A., Brouard, D. Evaluation of the red blood cell quality obtained from non-anemic donors with signs of iron deficiency.

Rochette, S., Lewin, A., Germain, M., Girard, M. Epidemiology of and treatments for ligneous conjunctivitis: A literature review amid a surging demand for plasminogen eye drops prepared by Héma-Québec.

Guest lectures

Bazin, R. Lymphopenia in plasmapheresis donors.

Cloutier, M. Héma-Québec's recent efforts on SARS-CoV-2.

Girard, M. The ups and downs of granulocyte research: looking for new ways to do things.

Laganière, J. Exploiting genome editing in transfusion medicine research/engineering blood cells for research and therapy.

Latour, C. Granulocytes concentrates at Hema-Québec.

Lemieux, W. The Québec blood bank experience: fulfilling the need for pediatric sickle cell disease patients and diminishing immunization risk.

Leiva-Torres, G. A. Transfusion management using blood group genotyping of children with sickle cell disease.

Lewin, A. Big data for epidemiological research in blood services.

Robitaille, N., Prokopchuk-Gauk, O. Hyperhemolysis: the forgotten transfusions reaction.

International Society of Blood Transfusion (ISBT) 2023 Annual Meeting, Gothenburg, Sweden, June 17-21, 2023

Oral presentations

Lewin, A. Pozzo di Borgo, A., Renaud, C., O'Brien, S., Delage, G., Germain, M. Risk assessment model for vCJD blood contamination.

Robidoux, J., Brouard, D. Quality of red cell concentrates from non-anemic donors with signs of iron deficiency.

Posters

Ducas, E., Cayer, M. P., De Grandmont, M. J., Riverin, P., Bourgoin, L., Lewin, A., Cloutier, M. Aggregates in Apheresis Platelet Concentrates: Can It Be Predicted From Donor's History.

Leiva-Torres G. A., Cigna, M., St-Louis, M., Perreault, J., Lewin, A., Pastore, Y., Robitaille, N. Transfusion management using blood group genotyping of children with sickle cell disease when the pool of Black donors is limited.

Lewin, A., Pozzo Di Borgo, A., Gaussen, A., Rochette, S., O'Brien, S., Germain, M., Renaud, C., Transmission of variant Creutzfeldt-Jakob disease through blood transfusion and plasma-derived products: A narrative review of observed and modelized risks.

Robidoux, J., Cayer, M. P., Dussault, N., Brouard, D. Flex capacity - multiple platelet concentrate preparation processes to maintain inventory level targets and respond promptly to crisis situations.

Guest lectures

Lewin, A. Big data for epidemiological research in blood services.

Lewin, A. Individualized risk assessment for gbMSM donors.

13th International Donor Registry Conference (IDRC) and WMDA Global Meeting, Frankfurt, Germany, June 18-21, 2023

Poster

Trépanier, P., Simard, C., Fournier, D. The importance of potency testing to determine cryopreserved stem cell products' fitness: Interpretation and performance of the IL-3pSTAT5 potency assay.

International Society for Experimental Hematology (ISEH) 2023 Annual Scientific Meeting, New York, United States, August 17-20, 2023

Poster

Boccacci, Y., Margaillan, G., Dumont, N., Dubé, P., Doyon, Y., Laganière, J. Ex vivo CRISPR-based sickle cell modeling.

Cord Blood Connect, Miami, United States, September 8–10, 2023

Poster

Simard, C., Fournier, D., Trepanier, P. Machine learning approach for automatic enumeration of cord blood stem cells by flow cytometry.

Association for the Advancement of Blood and Biotherapies (AABB) 2023 Annual Meeting, Nashville, United States, October 13–17, 2023

Oral presentations

Dubois, C., Robidoux, J., Masson, J. F., Brouard, D. Ferritin determination in blood using a point-of-care surface plasmon resonance sensor.

Kanias, T. Bean, S. Thomas, K. Dzieciatkowska, M. Yokoyama, A. H. Cognasse, F. Cloutier, M. Acker, J. Age and sex differences in the red blood cell proteome highlight how donor factors may impact blood product quality: The BEST collaborative study.

Product safety and efficacy, and donor safety

Support to operations

Lewin, A., Lemieux, W., Leiva-Torres, G. A., Cigna, M., Constanzo Yanez, J., Pastore, Y., Robitaille, N. Probability of finding partially or fully compatible blood for patients with sickle cell disease: A descriptive analysis of donor recipient genotype data.

Posters

Bazin, R., Lewin, A., Germain, M., Renaud, C., Grégoire, Y., Perreault, J. Humoral response to COVID-19 vaccination in frequent plasmapheresis donors.

Cigna, M., Leiva-Torres, G. A., Baillargeon, N., Constanzo-Yanez, J., Robitaille, N. Management of a Sickle Cell Disease Patient with Multiple Alloantibodies in Preparation for a Bone Marrow Transplant.

Dussault, N., Boyer, L., Cayer, M. P., Fonseca, S., Robidoux, J., de Grandmont, M. J., Brouard, D. A new thermoregulated container system for cold processing of whole blood donations in extreme climate conditions.

Lampron, M. C., Tremblay-Desbiens, C., Loubaki, L. Whole blood exposure to a cannabinoid mixture impairs the quality of red blood cells and platelets.

Maude, C., Leiva-Torres, G. A., Baillargeon, N., Constanzo-Yanez, J., Robitaille, N. Management of a sickle cell disease patient with multiple alloantibodies in preparation for a bone marrow transplant.

Robert, M., Roy, L., Lewin, A., Pigeon, C., Laroche, V., Paradis, K., Robitaille, N. Hospital and blood center collaboration to improve platelet delivery efficiency: Increased inventory without increased wastage.

Guest lecture

Robidoux J., Cayer M. P., Dussault N., DeGrandmont M. J., Brouard, D. The experience of Héma-Québec with the Reveos® system.



7th International Congress of the European Milk Bank Association (EMBA), Madrid, Spain, October 25–27, 2023

Poster

Laforce-Lavoie, A., Turgeon, A., Gaussen, A., Girard, M. Comparison and efficacy of breast pump cleaning techniques for bioburden reduction.

Convention of the Ordre professionnel des technologistes médicaux du Québec (OPTMQ), Lévis, Canada, November 3–4, 2023

Guest lectures

Baillargeon, N., Morin, P., Chaboillez, S. Les pratiques transfusionnelles : les problèmes rencontrés.

Cayer, M. P., Dussault, N., Robidoux, J., de Grandmont, M. J., Brouard, D. Développement et validation de systèmes thermorégulateurs pour le transport de produits sanguins et quelques autres projets.

Constanzo Yanez, J. Histoire d'un Bombay : de Mumbai jusqu'au labo.

Convention of the Société Francophone de Transfusion Sanguine, Toulouse, France, November 29-December 1, 2023

Oral presentation

Thibeault, C., Caruso, J., Otis, J., Germain, M., Lewin, A., Myhal, G., Monteith, K., Daunais-Laurin, G. Acceptabilité d'un questionnaire non genré chez les donneurs et les donneuses d'Héma-Québec et intention de retourner faire un don de sang.

65th American Society of Hematology Annual Meeting, San Diego, United States, December 9–12, 2023

Oral presentation

Kazadi, C., Robitaille, N., Forte, S., Ducruet, T., Pastore, Y. D. Positive impacts of the universal newborn screening program on the outcome of children with sickle cell disease in the province of Québec: A retrospective cohort study.

Other guest lectures

Cloutier, M. Pathogen inactivation of blood components. Réseau des associations vouées aux troubles sanguins rares. Ottawa, Canada. November 4, 2023.

Dieudé, M., Bazin, R. Les multiples visages de la recherche à Héma-Québec. Les Conférences Interaxes du CRCHUM. Montreal, Canada. March 10, 2023.

Dieudé, M., Normand, M. H. La néphrite lupique : au-delà du glomérule! Les Midis Plateformes, l'audace de chercher plus loin ensemble! Montreal, Canada. March 13, 2023.

Dieudé, M., Équipe du Projet Laurent. Le projet Laurent interdisciplinarité. Congrès de l'Association des médecins vétérinaires du Québec (AMVQ). Montreal, Canada. April 2, 2023.

Dieudé M. Héma-Québec partenaire de recherche. Séminaires scientifiques du Centre de recherche de l'Hôpital Maisonneuve-Rosemont. Montreal, Canada. May 12, 2023.

Dieudé M. Les visages de la recherche d'Héma-Québec. Séminaires Université du Québec à Trois-Rivières (UQTR) sciences biomédicales. Montreal, Canada. May 15, 2023.

Dieudé, M., Doré, I. Le projet Laurent. Table ronde Une seule santé. Montreal, Canada. June 6, 2023.

Dieudé, M. Vascular injury derived extracellular vesicles and auto-immunity. 5th Annual Québec Extracellular Vesicle Workshop. Montreal, Canada. November 21, 2023.

Dieudé, M. Humoral autoimmune responses triggered vascular injury derived extracellular vesicles. Symposium on autoimmunity, complement and tissue injury in transplantation. Montreal, Canada. December 8, 2023.

Latour, C. L'utilisation des concentrés de granulocytes pour le traitement des infections réfractaires. Congrès annuel de l'Association des médecins microbiologistes infectiologues du Québec. Sainte-Anne-des-Lacs, Canada. June 8, 2023.

Health of Québec's population

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Product safety and efficacy, and donor safety

Support to operations

Training and knowledge dissemination

Latour, C. Granulocytes transfusions in Canada. CBS Transfusion trainee seminars (virtual event). September 19, 2023.

Lewin, A. Blood providers and sero-epidemiology. Canadian Immunization Conference. Ottawa, Canada. April 25-27, 2023.

Robitaille, N. Anémie falciforme : définir et encadrer les traitements. Les Journées Montfort 2023 (virtual event). April 21, 2023.

Robitaille, N. Rare blood: implications for the patient. National Conference on Sickle Cell Disease 2023: Removing barriers to access care for the sickle cell community in Canada. Montreal, Canada. September 8, 2023.

Robitaille, N. Mission d'Héma-Québec et prévention des pénuries de produits sanguins. Café scientifique de médecine transfusionnelle. Minimiser le risque de pénurie des produits sanguins: l'affaire de tous. Montreal, Canada. September 20, 2023.

Robitaille, N. Équilibre entre l'autosuffisance et l'utilisation des immunoglobulins. Forum de Biovigilance 2023 — Rémunération des donneurs. Québec, Canada. 16 novembre 2023.

Patent

Methods for culturing and/or differentiating hematopoietic stem cells into progenitors and uses thereof. Divisional patent US 11,666,600 B2 granted in the United States on June 6, 2023. Laganière, J., Dumont., N,, inventors. Héma-Québec, assignee. Patent expiry: 2036-06-03.

Book chapter

Gardner, E., Fernandes, M., Latour, C., Seftel, M., Acker, J., Clarke, G. Chapter 20 — "Granulocyte transfusion therapy". In: Khandelwal, A., Abe, T., eds: Clinical Guide to Transfusion.

Outreach

Research partners

Funding



RESEARCH PARTNERS

Association professionnelle des chargés de sécurité transfusionnelle du Québec (APCSTQ)

The APCSTQ brings together Québec's transfusion safety officers whose work is vital to maintaining the highest standards of quality and improving transfusion practices. The support of the APCSTQ was essential in preparing the first edition of the immunohematology guide (<u>page 7</u>).

Biomedical Excellence for Safer Transfusion (BEST)

The BEST is an international collaborative of blood providers and industry and academic experts, who recommend procedures to improve operational and clinical practices in transfusion medicine and cell therapy. Among other projects, Héma-Québec collaborated with the BEST on a study on T-cell lymphopenia in platelet donors (page 22) and a multicentre study to better characterize red blood cells from teenage and senior donors (page 20). Other collaborations with the BEST are ongoing at Héma-Québec.

CARTaGENE

This public research platform of the Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine) pools the data and biological samples of 43,000 Québecers between the ages of 40 and 69, thereby accelerating the completion of countless health research projects. Héma-Québec was able to count on the participants and data from CARTaGENE to complete a project estimating the prevalence of weak D type 42 in the Québec population (page 11).

Centre de recherche du Centre hospitalier Universitaire de Québec - Université Laval (CRCHU de Québec-UL)

This network brings together five hospitals and the activities of the Centre de recherche du CHU de Québec-UL, which is known for the quality and originality of its basic, translational and clinical research teams. Several of the CRCHU de Québec-UL laboratories collaborate with our organization on genome editing projects, among others. Héma-Québec wishes to especially thank the staff of the Hôpital Saint-François d'Assise for the collection of cord blood for research.

Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM)

The CRCHUM is a research centre that brings together experienced scientists working in various fields associated with health improvement and covering a broad spectrum, from basic to clinical research. In the past year, the CRCHUM has positioned itself as a major partner in the completion of research projects on humoral immunity against SARS-CoV-2 (page 12).

The CHU Sainte-Justine is a health institution that — in addition to fulfilling its mission to provide care to Québec children, adolescents and mothers — is home to top-level research activities. Héma-Québec is privileged to be able to count on the collaboration of the CHU Sainte-Justine to document the prevalence and predictive factors associated with anemia in children who were hospitalized in intensive care (page 9) and to update the recommendations on the use of phenotyped blood (page 35). Héma-Québec collaborates with the CHU Sainte-Justine on several other projects.

Centre hospitalier universitaire de Sherbrooke (CHUS)

In addition to being a leader in medical research, the CHUS provides health care to the population. Our organization is proud to have been able to count on the expertise of the CHUS to update the recommendations on the use of phenotyped blood (page 35).

Centre LOEX

Located in Québec City, this centre is a leader in tissue engineering and regenerative medicine and has trained many researchers seeking to acquire leading-edge experience in this rapidly growing field. Héma-Québec was able to count on the expertise of LOEX on several projects completed in 2023.

Établissement français du sang (EFS)

The EFS is the public supplier of blood services in France. In addition to providing blood products, the EFS carries out scientific activities that have made it a vital player in innovation. Héma-Québec considers itself privileged to be able to benefit from the support of the EFS on several projects.

Fondation Émergence

The Fondation Émergence is a non-profit organization (NPO) whose mission is to educate, inform and raise awareness among the population on the plurality of gender identities and expressions and the realities of persons who see themselves in the sexual diversity. This NPO developed the awareness component of the training followed by Héma-Québec's staff on the gender-neutral questionnaire and organized a discussion group on the topic.

Innovation

Product safety and efficacy, and donor safety

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Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine)

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Funding



Imam Mohammad Ibn Saud Islamic University

Located in Saudi Arabia, the Imam Mohammad Ibn Saud Islamic University has a vast range of research capabilities in a diversity of natural science fields. It also boasts state-of-the-art facilities and a wealth of academic expertise, making it a key partner for the study of the effect of a mix of cannabinoids on the function of B cells (page 9).

Institut national de santé publique du Québec (INSPQ) and ministère de la Santé et des Services sociaux (MSSS)

The INSPQ is a centre of expertise in public health whose mission is to advance knowledge and formulate strategies aimed at improving the health and well-being of the Québec population. The MSSS provides health care and social services to the population of Québec to improve citizens' health and well-being. In 2023, Héma-Québec collaborated with the INSPQ and the MSSS on several studies dealing with COVID-19.

International Society of Blood Transfusion (ISBT)

The ISBT promotes knowledge sharing about transfusion medicine and provides professionals in this field with educational resources to optimize their clinical practice. During 2023, Héma-Québec collaborated with working groups from the ISBT on the completion of several projects, many dealing with the bacterial contamination of blood products.

Ordre professionnel des technologistes médicaux du Québec (OPTMQ)

The OPTMQ aims to protect the public by ensuring that its members provide quality medical laboratory services. Our organization had the pleasure of collaborating with this professional order in the preparation of the first edition of the immunohematology guide (page 7).

Réseau de thérapie cellulaire, tissulaire et génique du Québec (ThéCell)

The TheCell Network brings together more than 140 researchers (including several from Héma-Québec). Its aim is to promote potential cell, tissue and gene therapies developed by Québec universities. The network mobilizes and coordinates the players working in these fields to conduct clinical studies and make new therapies accessible to Québec patients. Héma-Québec is pleased to have collaborated with this network to organize a symposium on the opportunities and challenges related to advances in cell therapy and regenerative medicine (page 34).

Canadian Blood Services (CBS)

The CBS is Héma-Québec's counterpart and main supplier of blood products, cells and tissues in the rest of Canada. Héma-Québec has collaborated with the CBS for a long time, and 2023 was no exception, with a simulation study of the risks associated with the variant Creutzfeldt-Jakob disease (vCJD) (page 21) and the organization of an international symposium on the new eligibility criteria for blood donation for men who have sex with men (page 34). Héma-Québec is collaborating with the CBS on several other projects.

Université Laval

This university is a leading research centre in Canada and the world. The scientists affiliated with the Université Laval were partners of choice in a study aimed at assessing the effect of a mix of cannabinoids on the function of B cells (page 9) and several other projects.

Université du Québec à Montréal (UQAM)

Héma-Québec was able to count on the expertise of researchers from UQAM's Department of Sexology in implementing the gender-neutral questionnaire. UQAM's expertise proved vital in documenting the acceptability and feasibility of a plasma donation program intended for men who have sex with men and in the transition toward a gender-neutral pre-donation questionnaire.

Yale University

This American university is a world-class leader in research and development. The expertise of Yale's researchers was vital for studying the humoral immunity to SARS-CoV-2 (page 12).

Vitalant Research Institute (VRI)

This research institute is affiliated with Vitalant, one of the largest suppliers of blood products in the United States. VRI's mission is to advance the safety of blood products through research, education and policies based on sound data. Héma-Québec considers itself privileged to have collaborated with the VRI on numerous projects, including some linked with COVID-19.

World Marrow Donor Association (WMDA)

The WMDA is an NPO whose mission is to ensure a reliable supply of hematopoietic stem cells (HSC). The WMDA brings together registries, cord blood banks, donation centres, HLA experts, researchers and technologists working throughout the world. In doing so, this organization greatly facilitates the identification of compatible donations of high quality. Héma-Québec is proud to be associated with WMDA's SPEAR Committee in identifying the effects of the COVID-19 pandemic on the collection and administration of HSCs (page 23).

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Université de Montréal (UdeM)

The UdeM ranks as a first-class academic institution in Canada and the world, notably due to the quality of its research activities. Héma-Québec considers itself privileged to have been able to count on the many partners affiliated with this institution to study the humoral response to SARS-CoV-2 (page 12) and other projects of interest to our organization.

Outreach

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FUNDING

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Research grants have been awarded to many researchers for projects to which Héma-Québec has contributed.

\$120,000

Mitacs Elevate Grant awarded to a postdoctoral student under the supervision of Professor Andrés Finzi of the Centre de recherche du CHUM (academic supervisor) and Renée Bazin (industrial supervisor), valid from March 2023 to February 2025.

\$100,000

Mitacs Accelerate Grant awarded to a postdoctoral student under the supervision of Antoine Lewin (industrial supervisor) and Professor Ruth Sapir-Pichhadze of McGill University's Faculty of Medicine (academic supervisor), valid from February 2021 to February 2023.

\$95,000

Research grant from the Public Health Agency of Canada (PHAC) -COVID-19 Immunity Task Force (CITF) awarded to Renée Bazin (lead investigator) and Andrés Finzi (CRCHUM, co-lead investigator), valid from September 2022 to March 2023.

\$60,000 Mitacs Accelerate Grant awarded to a master's student under the supervision of Mélissa Girard (industrial supervisor) and Professor Maria J. Fernandes of the Centre de recherche du CHUQ (academic supervisor), valid from September 2021 to August 2023.







(NSERC) of Canada awarded to a master's student under the supervision

Grant from the Natural Sciences and Engineering Research Council of Professor Félix Camirand Lemyre of the Université de Sherbrooke (lead supervisor) and Antoine Lewin (industrial supervisor), valid from May 2022 to April 2023.

Support to operations Training and knowledge dissemination

\$27,000

Financial support from the Biomedical Excellence for Safer Transfusion (BEST) Collaborative.

Outreach

Research partners

Funding

RESEARCH ORGANIZATIONAL STRUCTURE AT HEMA-QUEBEC

More than fifty researchers leverage their knowledge to drive forward Héma-Québec's scientific activities.



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Vice-présidence aux affaires médicales et à l'innovation (Dr. Marc Germain, MD, FRCPC, PhD)

Provides medical, scientific and nursing expertise, in addition to monitoring activities, which enable the offering of services and safe biological products of human origin that integrate the most recent technological advances while ensuring the development and production of human tissues.

Direction médicale, microbiologie et épidémiologie (Dr. Christian Renaud, MD)

Follows up presumed cases of transfusion-transmitted infections.

Direction de l'exploitation des tissus humains (Étienne Fissette, BSc, MBA)

- Is responsible for collecting, processing, qualifying, storing and distr human tissues;
- Collaborates with the Direction de la recherche to develop new prod • and processing procedures for human tissues.

Direction scientifique (Renée Bazin, PhD)

- Supervises and supports all scientific activities within the Vice-prési aux affaires médicales et à l'innovation, as well as those of the rest of organization;
- Oversees the training program of the next generation of scientists.

Direction des opérations de recherche (Mélanie Dieudé, PhD)

- Contributes to improving knowledge through innovation projects in a activity sectors of the organization;
- Develops and contributes to projects in collaboration with university industry sectors locally, nationally and internationally;
- Carries out projects aimed at developing new products, tests and procedures;

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	 Develops and carries out projects in response to the technical or operational needs of the entire organization;
	 Provides scientific expertise to all sectors of the organization.
	Unité d'épidémiologie, de vigie et de gestion des risques biologiques (Antoine Lewin, PhD, MPH)
ibuting	 Leads epidemiological research projects;
ucts	 Is responsible for strategic monitoring in Héma-Québec's areas of activity;
	 Provides expertise on the management of risks associated with biological products of human origin prepared by Héma-Québec;
dence f the	 Provides scientific, biostatical and methodological support to the design, completion, testing and publication of scientific studies and research protocols.
	Direction des services infirmiers (Isabelle Rabusseau, inf)
all	 Ensures that blood components are collected in optimal conditions for the well-being of donors by applying the latest standards and knowledge to all the techniques used;
and	 Is responsible for inquiries about adverse reactions occurring during a donation;
und	 Answers donor questions about blood donation and types of collection, among others.

Outreach

Research partners

Funding



Vice-présidence à la médecine transfusionnelle (Dr. Nancy Robitaille, MD, FRCPC)

Provides testing, services and specialized products in transfusion medicine and stem cell transplantation that help hospitals and our international partners provide their patients with the care they need on a timely basis, in addition to participating in the production of educational material related to transfusion medicine.

Direction médicale, hématologie et cellules souches (Dr. Catherine Latour, MD)

- Supervises transfusion medicine fellows and is responsible for traini intended for resident physicians in hematology and oncology;
- Provides medical expertise in hematology and cell therapy;
- Participates in the donor selection criteria committee (including the • committee with Canadian Blood Services);
- Takes part in the assessment of declared transfusion reactions and evaluation of donors presenting with health problems that do not ap the selection criteria;
- · Helps manage rare blood cases by providing expertise in erythrocyt platelet immunology

Direction des cellules souches (Diane Fournier, PhD)

- Manages the activities of the Stem Cell Donor Registry, including th enrolment, qualification, search, selection and support of donors;
- Acts as a partner of international registries and collection and transp • centres in Québec to ensure a safe supply of stem cells;
- Oversees the operations of the Public Cord Blood Bank, including ٠ the enrolment and qualification of donors, collection of cord blood in partnership with hospitals, cryopreservation of the blood collected, inventory management, and product distribution;
- Provides a cryopreservation, storage and distribution service for autologous peripheral stem cells for four hospitals.

	Direction des laboratoires de référence (Marie-Claire Chevrier, MSc)
ing days	 Conducts specialized erythrocyte, platelet and leukocyte immunology (HLA) tests for hospitals;
	 Maintains an inventory of phenotyped and frozen packed red blood cells;
e joint	 Conducts HLA tests for the Stem Cell Donor Registry, Public Cord Blood Bank and Platelet Registry with compatible HLA profiles;
	 Selects specialized blood products that are compatible with patients;
the opear in	 Is responsible for the rare blood program
te and	Direction du partenariat clinique avec les centres hospitaliers (Marie-Hélène Robert, TM, RT)
	 Reinforces Héma-Québec's partnership role;
	 Develops a personalized client-centred approach based on the client's needs;
	 Makes the hospital viewpoint known regarding every project.
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