HÉMA-QUÉBEC

Research amid a pandemic

2020–2021 Scientific Activities Report

SUMMARY

This icon indicates scientific activities related to COVID-19.

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Dear Reader,

Héma-Québec is pleased to present the second edition of its scientific activities report, which covers the period from April 2020 to March 2021.

During this period, the COVID-19 pandemic was a major event that did not spare Héma-Québec, its employees and partners. Our operational and research activities were disrupted to a degree never seen before.

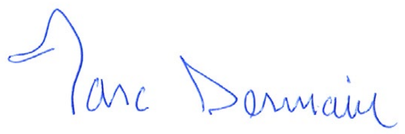
Despite all the uncertainty surrounding this situation, our organization proved to be remarkably flexible. Staff tasked with research activities were initially redeployed to blood drives to ensure the continued supply of blood products. Subsequently, all research activities were directed at assisting public health authorities in conducting COVID-19-related studies. As a supplier of blood products, Héma-Québec was the ideal partner to conduct these studies to meet the scientific needs of governments, government departments and universities. More than ever, our organization distinguished itself by its commitment and role in Québec society.

This was especially evident through Héma-Québec's participation in two randomized, controlled studies that aimed to evaluate the safety and efficacy of convalescent plasma in patients with COVID-19 (CONCOR-1 and REMAP-CAP studies). One study was also conducted in collaboration with the Institut national de santé publique du Québec (INSPQ) to evaluate the progression of anti-SARS-CoV-2 seroprevalence in the Québec population. The information provided by this study helped facilitate decision-making regarding health measures, modelling of the epidemic, and planning of the vaccination campaign. Finally, a study conducted in collaboration with the Groupe de travail sur l'immunité face à la COVID-19 (GTIC) is currently recruiting frequent plasma donors to better understand the evolution of the immune response to SARS-CoV-2 and vaccine response, and to document the risk of reinfection. Samples collected as part of this study will be stored in a biobank and thus be available to the entire scientific community for future studies.

While major efforts were devoted to COVID-19 projects and the temporary interruption of some work, our teams quickly resumed activities directly related to their supportive role to the organization's product lines and services. Despite the scope of this report, it does not describe all these projects. I am especially proud of the progress made to advance them at a time when all our attention was monopolized by COVID-19.

The projects summarized in this report are the fruit of a collaboration between experienced clinicians and researchers working within the organization. Research and development are paramount to enabling Héma-Québec to maintain the highest standards of quality in its operations, developing new products, and sustaining its international profile. On behalf of management, I would like to thank all those who contributed to Héma-Québec's many successes in this pandemic year.

I wish you happy reading.



Dr. Marc Germain, MD, FRCP(C), PhD
Vice President, Medical Affairs and Innovation

HIGHLIGHTS

Héma-Québec took part in two clinical studies (CONCOR-1 and REMAP-CAP) that aimed to document the efficacy of convalescent plasma in patients with COVID-19

An anti-SARS-CoV-2 seroprevalence study was conducted in Québec in collaboration with the Institut national de santé publique du Québec (INSPQ)

As part of its efforts to continue research into immunity to COVID-19, Héma-Québec initiated a project to establish a biobank of samples from frequent plasma donors (PlasCov)

41 PUBLICATIONS

10 GUEST LECTURES

6 ORAL PRESENTATIONS

10 POSTERS

1 WORKSHOP IN AN INTERNATIONAL CONFERENCE

18 INTERNAL REPORTS

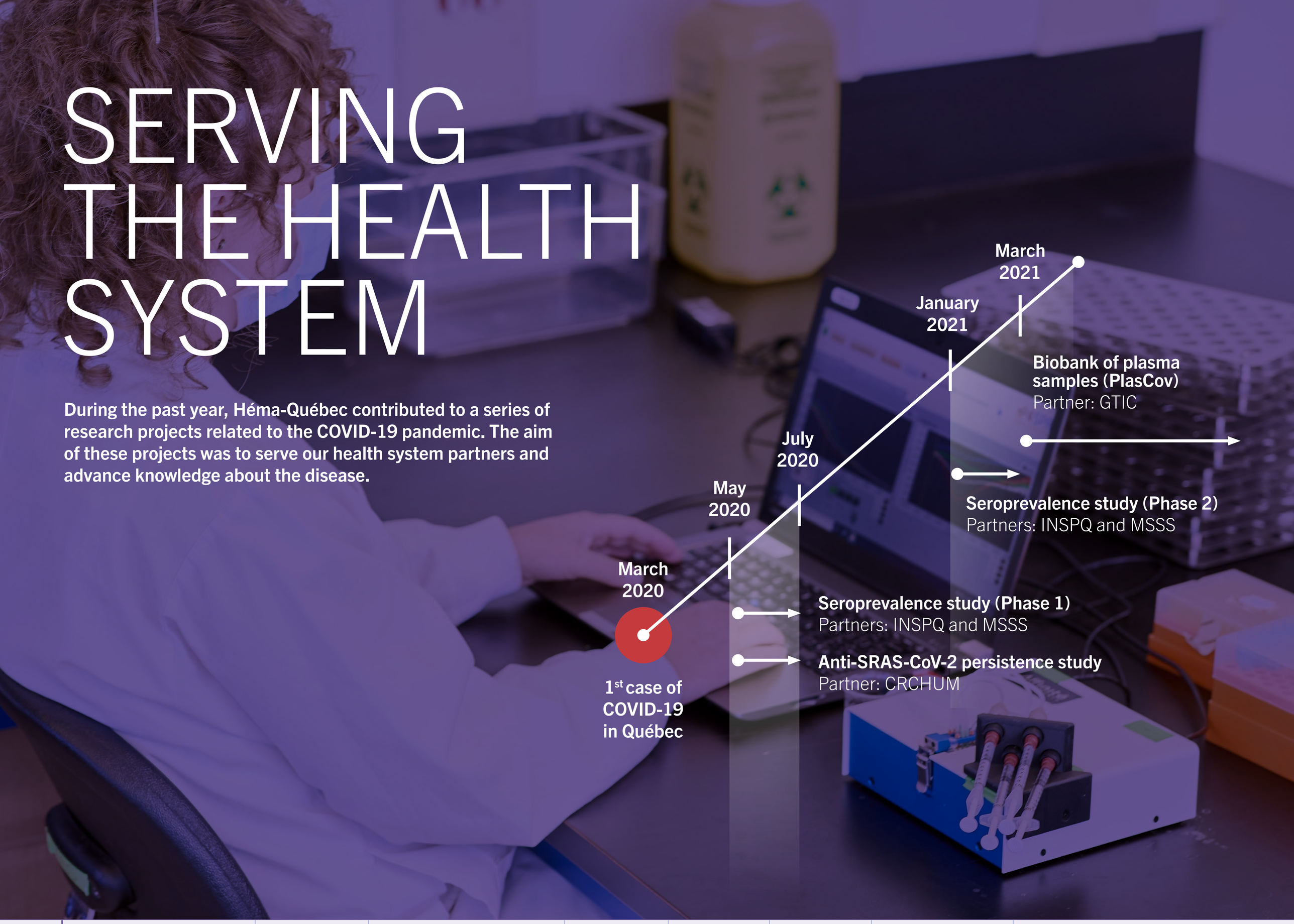
Two literature reviews revealed that the risk of transmission of SARS-CoV-2 through the transfusion of blood products or cell, tissue or organ transplantation remains theoretical

An analysis of plasma samples from the CONCOR-1 study showed that, in most individuals, the levels of antibodies to SARS-CoV-2 significantly decreased four months after the onset of disease symptoms

A literature review showed that several strategies implemented by blood banks helped maintain equitable access to blood products despite the unpredictable demand for and supply of blood products during the pandemic

SERVING THE HEALTH SYSTEM

During the past year, Héma-Québec contributed to a series of research projects related to the COVID-19 pandemic. The aim of these projects was to serve our health system partners and advance knowledge about the disease.



Evaluation of the efficacy and safety of convalescent plasma as a treatment for COVID-19: CONCOR-1 and REMAP-CAP studies

Plasma from individuals who have recovered following an infection (convalescent plasma) can be useful in treating various viral infections. However, there is little data supporting its use for the treatment of COVID-19.

Héma-Québec contributed to two randomized, controlled clinical trials. The objective of these trials was to study the effect of convalescent plasma on hospitalized patients with COVID-19 (CONCOR-1 Study) and seriously-ill patients with the disease (REMAP-CAP Study). An interim analysis of the data from both studies revealed a lack of efficacy in the populations studied. The clinical trials were therefore halted. Analyses are under way to determine if other patient groups could benefit from this treatment. Héma-Québec wishes to thank all the donors who took part in this project. Their mobilization helped advance research aiming to develop better protocols for treating patients with COVID-19.

Seroprevalence study of antibodies to SARS-CoV-2 in Québec

Decisions related to COVID-19 health restrictions must be informed by evidence providing an accurate picture of the epidemiological situation. By their very mission and expertise, blood banks are in an ideal position to conduct COVID-19 seroprevalence studies and to inform public health decision-makers about the scope of the pandemic.

A study was conducted in collaboration with the Institut national de santé publique du Québec (INSPQ) and the ministère de la Santé et des Services sociaux (MSSS) to evaluate the seroprevalence of antibodies to SARS-CoV-2 in the Québec population. The first phase of the study, carried out in May and June 2020, revealed a seroprevalence rate of 2.23% among Héma-Québec's blood donors. The results of this study were published in the *Canadian Journal of Public Health*. The second phase, carried out between January and March 2021, showed that the seroprevalence rate was now 14.72% in the overall population (including vaccinated individuals) and 10.52% in the unvaccinated population. The study also showed that some ethnic groups were disproportionately affected by COVID-19. These data suggest that more than one out of three COVID-19 cases escape detection by public health initiatives. Finally, the study made it possible to estimate that almost 20% of the proportion of individuals observed had seroreverted (i.e., passage from a seropositive to a seronegative state) in the months following recovery from the infection, an estimate that should help interpret future seroprevalence studies of COVID-19.

Effects of the COVID-19 pandemic on supply and use of blood products for transfusion

The COVID-19 pandemic has had major implications for the supply of blood products and other biological products of human origin. Demand for blood products, for exemple, fluctuates unpredictably, and blood banks need to consider possible reductions in donations and loss of staff due to illness and health restrictions.

A literature review was done to identify solutions to these logistical challenges. Identified studies suggest that a reduction in donations resulting from the pandemic was accompanied by an equivalent reduction in the demand for blood products. In the event of a major decrease in blood reserves, potential continuity plans should include a system for prioritizing patients. Several strategies identified in the review and used by most blood banks maintain equitable access to blood products, in addition to providing potential new treatments, such as convalescent plasma. The results of this study were published in *Lancet Haematology*.

Proportion of the adult population in Québec that developed antibodies directed against SARS-CoV-2

FIRST PHASE	SECOND PHASE
2.23%	14.72%

Presence of SARS-CoV-2 RNA in blood products from pre-symptomatic donors at the time of donation

In response to the COVID-19 pandemic, Héma-Québec adopted a series of measures to reduce the theoretical risk of transmission of SARS-CoV-2 by blood transfusion. For example, donations from individuals who reported COVID-19 symptoms after donating were systematically removed from inventory, regardless of whether a diagnosis of COVID-19 was confirmed or not.

The results of this study suggest that SARS-CoV-2 viral loads are very low and not infectious. The risk of COVID-19 transmission through blood transfusion should, therefore, be negligible.

The objective of this study was to evaluate the levels of SARS-CoV-2 viral RNA in individuals diagnosed with COVID-19 after donating blood. As of March 10, 2020, six cases had been identified, and no product from these donors was transfused. Samples from these donors were sent to four independent laboratories to quantify the levels of viral RNA. Viral RNA was detected in only one of the six samples, and the quantity was so low that two of the four laboratories did not detect it. Furthermore, the viral load present in this donation appeared to be insufficient to potentially transmit the infection, as suggested by the absence of viral replication found by incubating a cell line with the sample. The results of this study, published in the journal *Transfusion*, suggest that SARS-CoV-2 viral loads are very limited and not infectious in the blood of pre-symptomatic donors at the time of donation. The risk of transmitting COVID-19 through a transfusion should, therefore, be negligible.

Data on the risk of transmission of SARS-CoV-2 by transfusion

With the emergence of SARS-CoV-2, there were fears that the virus could be transmitted by transfusion, as suggested by the presence of viral RNA in the blood of some individuals.

To evaluate this risk, a literature review was done to systematically identify studies that had reported data on the presence of viral RNA in blood. In all, 23 studies were retained. Three of these studies reported cases of donors diagnosed with COVID-19 after donating; no case of transmission by transfusion was subsequently revealed in these studies. Although several studies confirmed the presence of infectious particles of SARS-CoV-2 in cell lines infected with respiratory samples from individuals with COVID-19, none showed any infectious potential in the blood, even among individuals with elevated viral RNA loads. Furthermore, the results of some studies suggested that a minimum viral load threshold is necessary to establish infection. This threshold is rarely reached in blood or specific blood components. Together, these data suggest that the risk of transmission of SARS-CoV-2 by blood transfusion is theoretical. The results of this study, which was led by Héma-Québec, were published in the journal *Transfusion*.

Data emanating from various studies suggest that the risk of SARS-CoV-2 transmission through blood transfusion is theoretical.

Data on the risk of SARS-CoV-2 transmission through stem cell, tissue and organ transplantation

In the wake of the arrival of SARS-CoV-2, agencies overseeing donations and transplantation of cells, tissues, and organs were worried about the possible transmission of the virus by transplantation. The signs and symptoms observed in patients with COVID-19 gave rise to concerns that the virus could affect organs other than the lungs and be transmissible by transplantation. In addition, transplant recipients were especially vulnerable to complications from COVID-19 due to their immunocompromised state. Consequently, the clinical consensus was for donations from infected living or deceased individuals to no longer be accepted, thus extending wait times for recipients.

To evaluate the risk of transmission of SARS-CoV-2 by transplantation, a literature review was done to identify cases of cell, tissue or organ transplantation involving a COVID-19-positive donor. Current knowledge about the detection and replication of the virus in various biological specimens was also summarized. The analyzed data suggest that SARS-CoV-2 can replicate in some cells, tissues and organs, which does not exclude the possibility of transmission by transplantation. However, most of the studies concentrated on the potential of transmission under experimental conditions, and their results were often contradictory, which complicates the comparison of results. In future, improved standardization of screening practices and systematic follow-up of recipients could facilitate assessment of the risks of transmission of SARS-CoV-2 by transplantation. The results of this study, which was led by Héma-Québec, were published in the journal *Transplantation*.

International comparison of the prevalence and incidence of human immunodeficiency virus (HIV) in blood donors and the general population—a BEST study

The efficacy of the measures in place to mitigate the risk of transmission of human immunodeficiency virus (HIV) by transfusion may vary from one jurisdiction to another. This could result, among other things, in differences in the epidemiology of HIV in blood donors compared with the general population.

The objective of this international study, launched by Héma-Québec within the scope of the consortium Biomedical Excellence for Safer Transfusion (BEST), was to compare the prevalence and incidence of HIV in blood donors and the general population in various jurisdictions. In the end, the correlation between the prevalence of HIV in new blood donors and the general population was modest. Furthermore, there was no correlation between the rates of HIV-positive donations among existing donors (i.e., incidence) and the general population. Canada registered a relatively low prevalence and incidence of HIV compared with the other regions analyzed. These data, which were published in the journal *Vox Sanguinis*, show that the prevalence and incidence of HIV is generally low in blood donors. The countries that allow men who have sex with men to give blood posted a greater prevalence and incidence of HIV, but given the measures currently in place, the risk remains low for recipients.

These data show that the prevalence and incidence of HIV is generally low in blood donors.

Implementation of a new fluorometric immunoassay using Luminex polystyrene beads to identify anti-HLA Class I and II antibodies

The proteins in the human leukocyte antigen (HLA) system can be the target of antibodies produced during pregnancy, following transfusion of certain blood products, or after an organ transplant. These antibodies can cause the rejection of a graft when a stem cell or solid organ graft (under some conditions) interferes with the transfusion of platelets.

In response to recent technological developments, Héma-Québec evaluated two new test kits approved by Health Canada and compatible with the Luminex fluoroanalyzer to identify Class I and II HLA antibodies. The method validation, including accuracy, reproducibility and precision tests, along with an interlaboratory evaluation, showed that the kits meet the required performance levels. Consequently, these new kits were approved by the accrediting agency (American Society for Histocompatibility and Immunogenetics) and installed in the Reference Laboratories.

Comparison of the reactivity of several commercial anti-D reagents on samples of individuals presenting with a weak or partial RhD phenotype

The RhD system is second only to the ABO system as the most important blood group antigen system in transfusion medicine. Identifying the RhD phenotype of an individual is important to know the individual's eventual blood product needs. For pregnant women, this information is vital to prevent cases of alloimmunization or mother-fetus incompatibility. Identifying the RhD phenotype can, however, be complex. Conventional methods can generate results that are conflicting or difficult to interpret, sometimes requiring further testing.

Given its recognized expertise in this type of testing, Héma-Québec partnered with various reference laboratories to compare the reactivity of various commercial anti-RhD reagents on samples from individuals with a weak or partial RhD phenotype (confirmed by genotyping). Preliminary results seem to confirm that the performance of serological tests using reagents from various manufacturers is insufficient to correctly identify weak or partial RhD phenotypes. In these cases, genotyping is necessary.

Nancy Robitaille, Vice President, Transfusion Medicine

Prevalence of weak D type 42 phenotype observed in a large-scale *RHD* genotyping program in Québec

Identifying an RhD phenotype is vital to preventing alloimmunization, especially in pregnant women. A large-scale genotyping program was implemented in Québec in 2015 and is offered to women aged 45 and under with a weak D phenotype or conflicting results between various tests. The prevalence of weak D type 42 is relatively high among persons of European descent.

A province-wide, *RHD* genotyping program helps document polymorphism at the *RHD* locus among women aged 45 years or younger.

The objective of this study was to describe the *RHD* profile of women who had been genotyped at the Reference Laboratories between 2016 and 2020 and presented with a weak D phenotype. The testing done took into account the genetic profile and place of residence of these women. Type 42 showed a prevalence of 17.5% and was the most frequent weak D phenotype among the 2,105 women included in the study. Furthermore, this variant was especially prevalent in regions with a low rate of immigration, which suggests the presence of a founder effect. These data were published in the journal *Transfusion* and have helped better document the polymorphism of the *RHD* locus in women aged 45 or under.

Project on the strategic monitoring of biological products (Pro-VISTA)

In a context of constantly evolving science and technology, it is essential to quickly identify the latest innovations and to monitor their impact on Héma-Québec's operational practices. Such monitoring can help increase the quality of the services offered and the organizational efficacy, as well as inform strategic decision-making.

Given these potential advantages, a project on the strategic monitoring of biological products (Pro-VISTA) was formed. More specifically, the aim of Pro-VISTA is to be attuned to the latest developments regarding biological products of human origin and the progress made in laboratory testing and technological platforms. Mobilizing internal expertise and resources has helped identify products, tests and platforms of interest, and to classify them in order of priority based on objective criteria. Furthermore, a state-of-the-art review of each chosen topic was conducted to implement scientific and strategic monitoring. Regular monitoring can now be done to support the committee tasked with evaluating their strategic scope.

Renée Bazin (second from the left) with members of the research team.

INNOVATION

Héma-Québec's research activities help advance knowledge and the development of new technologies. The projects in this section relate to several innovations to which Héma-Québec contributed this past year.

Evaluation of a point-of-care intervention to detect antibodies against SARS-CoV-2 by surface plasmon resonance

Surface plasmon resonance (SPR) directly measures antibodies in serum, plasma and dried human blood spots. This method relies on the measurement of a variation of the refractive index (at the interface between a fine metal layer and the biological medium) in response to a receptor–ligand interaction.

An approach based on surface plasmon resonance enabled the development of reliable serological tests that could identify individuals who had contracted SARS-CoV-2.

In the wake of the arrival of the COVID-19 pandemic, a collaborative project, bringing together researchers from the Université de Montréal, the Université Laval, Affinité Instruments and Héma-Québec, was launched to develop an SPR approach capable of detecting antibodies to SARS-CoV-2. Performances of this testing approach were compared with those of the reference method (ELISA). The study recruited 32 individuals who had tested positive for COVID-19 but were not hospitalized for the disease. IgG concentrations in both methods decreased with time after the infection. In addition, the IgG concentrations positively correlated with the age of the individuals. This project made it possible to develop reliable serological tests that could identify individuals who had contracted SARS-CoV-2 and ultimately help prevent the spread of the disease. The results of this project were published in the journal *Analyst*.

Effect of the selective depletion of certain antibody isotypes against SARS-CoV-2

Héma-Québec and the Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM) were among the first to show that the neutralizing activity of convalescent plasma against COVID-19 (i.e., plasma from patients who had recovered from COVID-19) rapidly decreases in the first weeks following recovery. Furthermore, specific classes of antibodies (e.g., IgA, IgG and IgM) could influence the activity of convalescent plasma in different ways.

This study, which is the fruit of a collaboration between the CRCHUM, the Western University, the Groupe de travail sur l'immunité face à la COVID-19 (GTIC) and Héma-Québec, aimed to characterize the role of various classes of antibodies to SARS-CoV-2. To achieve this, the IgA, IgG and IgM present in samples of plasma from a cohort of convalescing patients were selectively depleted, following which the neutralizing power of the resulting plasma was measured. This approach revealed that the depletion of IgM (and, to a lesser degree, of IgG) was associated with a major reduction in the neutralizing power of the plasma, highlighting the major role of the IgM in immunity against COVID-19. This discovery,

This study demonstrated that the depletion of IgM (and, to a lesser degree, of IgG) significantly reduced the neutralizing power of convalescent plasma, highlighting the major role of IgM in immunity against COVID-19.

which was published in the journal *Cell Reports*, could contribute to the development of therapeutic antibodies. This could also explain the increased susceptibility of patients with autoimmune diseases receiving therapies that impair the production of IgM.

Persistence of the humoral response to SARS-CoV-2

Persons infected with SARS-CoV-2 normally develop antibodies to the virus. Since the start of the pandemic, the question of the persistence of these antibodies following recovery from the infection has generated a great deal of interest. At Héma-Québec, levels of antibodies against the receptor binding domain (RBD) of the spike protein were measured using an ELISA test developed in collaboration with the team from the Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM).

The objective of this project was to study the evolution of levels of RBD antibodies in convalescent plasma donors recruited in the CONCOR-1 clinical trial (see page 6). The results showed how levels of RBD antibodies begin to decrease approximately four months after the onset of symptoms of the disease in a vast majority of donors included in the study. Data were published in the journal *Blood*. This project, which will continue next year, will help assess the persistence of RBD antibodies over the longer term.

Research initiatives undertaken by blood product providers in response to the COVID-19 pandemic

Although COVID-19 is not transfusion-transmissible, the impact of the pandemic on the distribution of blood product services around the world has been complex. By virtue of their mission, blood product providers can contribute to certain research initiatives related to the pandemic, such as studies on convalescent plasma and on the seroprevalence of SARS-CoV-2.

A study conducted in collaboration with several blood banks (including Canadian Blood Services) aimed to identify the various COVID-19 research programs launched by blood banks in 62 countries. Results show that seroprevalence studies are planned or in progress in 73% of the countries. Furthermore, 79% of the countries surveyed have initiated programs to evaluate the efficacy and safety of convalescent plasma in treating COVID-19. The results of this study, which were published in the journal Vox Sanguinis, show the scope and speed of the research efforts conducted by blood banks in response to the pandemic.

International comparison of anti-SARS-CoV-2 assays used by blood banks to determine the seroprevalence of the virus

Blood banks are well positioned to conduct anti-SARS-CoV-2 seroprevalence studies. While many seroprevalence studies have been published since the start of the pandemic, in the absence of a "gold standard", a comprehensive view of the assays used by blood banks to measure the seroprevalence of anti-SARS-CoV-2 is missing.

The objectives of this study conducted in collaboration with the Public Health Agency of Canada (PHAC) were to evaluate the diversity of anti-SARS-CoV-2 assays being used by blood banks and to determine how this could affect seroprevalence estimates (38 blood banks provided details of the assays used). The documented assays differed in several aspects, in particular the nature of the tests (commercial or in-house), the classes of antibodies detected, the SARS-CoV-2 antigen targeted, and the specificity and sensitivity of the assays. These data suggest these differences are important when interpreting the results of seroprevalence studies. The data from this study were published in the journal *Vox Sanguinis*.

Study of HLA genetic profiles in units of cord blood and recipients to provide rapid access to cord blood stem cell transplants

The company ExCellThera is currently pursuing several phases of clinical development of its ECT-001-CB technology, which makes it possible to expand cord blood stem cells *in vitro* to make this type of transplant accessible to a much larger pool of patients. As part of this clinical development, ExCellThera finetuned a selection algorithm of a relatively limited number of HLA profiles covering a broad range of donor-recipient compatibilities.

To test this algorithm, ExCellThera entered into a collaborative agreement with Héma-Québec to access non-nominal HLA data of cord blood units banked by Héma-Québec. The objective of this analysis of non-nominal data is to select a pool of cord blood units whose HLA profiles will meet most of the needs of future clinical testing. The selected units will be expanded by the ECT-001-CB technology even before a transplant request is received from a clinician, making the units of cord blood quickly available for transplantation in patients during future clinical testing. This collaboration between Héma-Québec and ExCellThera (a Québec company) will enhance the Public Cord Blood Bank for the benefit of people here and abroad.

A collaboration between Héma-Québec and ExCellThera, a Québec company, will enhance the Public Cord Blood Bank for the benefit of patients here and abroad.

Measurement of the functionality of hematopoietic stem cells from fresh cord blood using an IL-3 response test

The conditions used before, during and after the cryopreservation of hematopoietic stem cells (HSC) from cord blood can significantly influence the quality of the final product and the chances of a successful transplant. However, the test to measure the regeneration potential of a unit of HSC, consisting in a colony-forming unit assay, requires up to two weeks of incubation, which can delay the transplant and compromise the patient's health. A rapid test (under 24 hours), based on stimulating HSC with IL-3, previously showed high reliability for measuring the functionality of thawed CD34+ HSC and could remedy this problem.

Adapting this test to fresh cells and their use has revealed major differences in several preservation parameters prior to the cryopreservation of the HSC from cord blood. HSC that were preserved for less than 24 hours were 22% more reactive to IL-3 compared with those preserved between 24 and 48 hours. Furthermore, the HSC were 14% (with a delay of less than 24 hours) to 23% (with a 24- to 48-hour delay) more reactive to IL-3 when preserved at 4°C compared with room temperature. These results suggest that testing based on the HSC response to IL-3 is a sensitive and reliable method for evaluating the functionality of HSC from freshly collected cord blood. Furthermore, preservation time and temperature seem to be key parameters that influence the quality of the product after cryopreservation.

Development of an *in vitro* test to measure the osteoinductive ability of the demineralised bone matrix

Demineralised bone matrix (DBM) is currently used as a substitute for bone grafting in orthopedics and dentistry. Several studies have shown that the ability of DBM to induce bone formation (osteoinduction) varies based on the donor's age and sex, the implantation site, the preparation method used, and other factors. While athymic mice are the best animal model to assess osteoinduction, this test is lengthy (28 days) and costly. It is important, therefore, to develop more rapid and less costly tests to ensure the functionality of the DBM after its manufacture.

The objective of this project was to develop an *in vitro* test that could evaluate the osteoinductive ability of DBM produced by Héma-Québec. Specifically, this new test evaluated the presence of bone morphogenetic proteins in DBM. Once developed, the test was compared with the standard method that used athymic mice. The ability of DBM to promote the differentiation (in culture) of myoblasts in bone cells was also evaluated by means of alkaline phosphatase activity, a marker of osteogenic activity. Our results showed a strong correlation between, on the one hand, alkaline phosphatase activity and, on the other hand, 1) BMP-7 (another marker of osteogenic activity) and 2) results of the murine test. Based on these results, the cell assay used to measure alkaline phosphatase activity is a valid alternative to the murine test to assess the osteoinductive ability of DBM.

Characterization of the analytical performance of a surface plasmon resonance method to quantify IgA compared with the current ELISA method

Selective deficiency in immunoglobulins A (IgA) is characterized by an abnormally low concentration of plasma IgA. Héma-Québec uses the ELISA method to 1) screen IgA-deficient donors and maintain an inventory of IgA-deficient plasma and 2) assist hospitals in diagnosing this deficiency in recipients who previously had a severe allergic reaction to a blood product.

The objective of this project was to develop a screening method using surface plasmon resonance (SPR) to quantify the IgA levels directly in serum and plasma. The analytical performance of this method was compared with that of ELISA. A calibration curve was generated using IgA-depleted serum, and a strong correlation was observed between the SPR instrument's response and the concentration of IgA for values ranging from 63 ng/mL to 1,000 ng/mL. These results were comparable to those obtained by ELISA. This study established a proof of concept aiming to show that SPR can be adapted to detect biological targets, such as IgA, in complex matrices.

Improvement of a method for *in vitro* production of red blood cells

A major objective of transfusion medicine is the *in vitro* production of red blood cells from hematopoietic stem cells (or other cell sources). Standard production protocols help achieve rapid growth of erythroid progenitors and high levels of reticulocyte enucleation. Nevertheless, these protocols do not efficiently reproduce the last step of erythropoiesis, i.e., the final maturation of reticulocytes into erythrocytes. However, accurately reproducing this step is essential to study diverse phenotypes and the maturation process, in addition to being ideal for the eventual use of these red blood cells for transfusion.

The improvement of a method allowing for the *in vitro* production of red blood cells paves the way to large-scale, potential applications, should partners with the necessary expertise and facilities be interested in pursuing this.

A culture medium and procedures were developed to maximize the yield of red blood cells and to reproduce the final maturation stage following differentiation of the hematopoietic stem cells. The composition and properties of the red blood cells resulting from this optimized procedure were very similar to those of red blood cells produced by the human body. These cells can be preserved for 42 days in a nutrient solution, a significant improvement over the 28 days typically achieved with standard protocols. Furthermore, this shelf life meets the time constraints facing blood banks. This promising breakthrough bodes well for the study of erythropoiesis and red blood cell phenotypes. It also suggests a possible application in the large-scale production of red blood cells, should partners with the necessary expertise and facilities be interested in pursuing this.

Application of the protocol for *in vitro* production of red blood cells: gene editing for the production of rare blood

Recent progress in the field of gene editing using CRISPR-Cas9 technology offers many opportunities to develop research tools and new treatment options. A CRISPR-Cas9 editing protocol (without a viral vector and selection) was optimized to genetically modify hematopoietic stem cells. When combined with a method to produce red blood cells, this protocol makes it possible to create, model and correct red blood cell phenotypes of interest to transfusion medicine.

Combined with a genome-editing technique, a protocol for the *in vitro* production of red blood cells enabled the deletion of the *ABO* gene, producing group O red blood cells. This breakthrough paves the way for transfusion applications.

As proof of concept of the feasibility of this approach, red blood cells from the Rh^{null} blood group were created by deleting the *RHAG* gene. While extremely rare, this blood group is of great scientific interest since it could theoretically be used to transfuse recipients with any Rh variant, as well as being very useful as a control reagent in serology. Similarly, the *ABO* gene was deleted from hematopoietic progenitor stem cells collected from group A or B donors, producing group O red blood cells. The complete absence of the residual expression of types A and B antigens in red blood cells suggests transfusion applications. For example, the approach could be used in compatible donors and recipients for rare phenotypes (e.g., RhD, RhCE) who are incompatible with the ABO system.

Sickle cell anemia: *in vitro* modelling and evaluation of the potential of autologous hematopoietic curative therapies

Gene editing of hematopoietic stem cells (HSC) has many potential applications for the study and treatment of sickle cell anemia, the most common monogenic disorder in humans. On the one hand, this approach could make it possible to model the disorder in the laboratory. On the other hand, it could improve our understanding of the potential repercussions associated with the clinical use of gene editing (e.g., genetically modified autologous stem cell transplants) on the characteristics of stem cells and red blood cells.

To model sickle cell anemia in red blood cells produced *in vitro*, the HBS mutation that causes the disorder was introduced into HSC that were then differentiated into mature red blood cells. The resulting protocol helped obtain cells that adopted a sickle shape once exposed to physiological levels of oxygen (8% O_2). This model could be used to study certain aspects of the disorder *in vitro* and be a proof of concept of the efficacy of combining the protocol for producing red blood cells and gene editing.

In addition, normal HSC (that do not carry the mutation) were used to better understand the effect of certain gene therapies (currently evaluated in phase 1 and 2 clinical studies) using gene editing to correct sickle cell anemia. One of the investigative strategies unexpectedly introduced new mutations into the globin gene, which warrants further research given its possible future therapeutic use.

Comparative study of commercial kits to predict the fetal *RHD* genotype using a non-invasive prenatal test performed on the mother's blood

Incompatibility of the RhD blood groups of the mother and fetus can result in serious consequences, such as hemolytic disease of the newborn. To reduce these risks of complications, all RhD negative (RhD-) pregnant women receive intravenous injections of anti-RhD immunoglobulin at week 28 of their pregnancy to prevent the mother's alloimmunization to the RhD antigen (in the event that the fetus is RhD+) and eventual complications during subsequent pregnancies. The progress made in recent years has made it possible to develop non-invasive tests to detect the fetus DNA circulating in the mother's blood. This new option helps identify mothers who are carrying an RhD- fetus in whom immunoglobulin injections could be avoided.

The objective of this project was to evaluate the commercial kits used to identify the fetal *RHD* genotype using a blood sample taken from the mother. In collaboration with the Centre hospitalier universitaire (CHU) Sainte-Justine and the Centre hospitalier de l'Université de Montréal (CHUM), a protocol was implemented to collect blood samples from pregnant women. In all, 18 blood samples were tested using three commercial kits. The results were generally consistent between the various kits and with the serological tests performed at the birth of the baby. A more comprehensive performance evaluation is planned to allow for the eventual implementation of this test across Québec.

Determinants of the intention to participate in a plasma donation program for fractionation among men who have sex with men

Several approaches are currently being studied to allow men who have sex with men (MSM) to donate blood. One of these approaches is a program of plasma donation for fractionation, with a quarantine period.

The objective of this study was to identify factors determining the intention of MSM to participate in such a program. The 993 MSM who accepted to take part in the study answered a questionnaire developed in collaboration with experts. The main factors predicting the intention to participate in the program were the participants' attitude to blood donation, their perception of the complexity of donating, being under the age of 35, having previously donated blood, others' perception of blood donation, an annual income of over $40,000, the compatibility of blood donation with participants' values, and active involvement in LGBTQ+ social causes. These results highlighted factors, several of which are related to the theory of planned behaviour, that can influence the decision of MSM to give blood as part of a program of plasma donation for fractionation, with a quarantine period. The study's results were published in the journal *Vox Sanguinis*.

Persistent lymphopenia in platelet donors by apheresis—a BEST study

At Héma-Québec, blood platelets destined for transfusion are generally produced using a process called thrombopheresis, a procedure that separates platelets from the other cells in the blood, which are then returned to the donor. Despite the return of these other components, a leukocyte reduction step reduces the amount of white blood cells returned. A recent study revealed that some frequent platelet donors showed signs of lymphopenia and, more specifically, a reduction in the number of CD4+ T lymphocytes (<200/µL). However, this phenomenon does not appear to be associated with health problems.

Against this backdrop, Héma-Québec participated in the BEST-PAL project, a study launched by the Biomedical Excellence for Safer Transfusion (BEST) group to expand these observations to a larger number of donors. Between October and December 2019, 30 frequent apheresis platelet donors were recruited, and their levels of T lymphocytes were monitored at regular intervals for a year. Ten per cent of eligible participants showed signs of lymphopenia, and more than half showed levels of T lymphocytes below normal values. The levels of T lymphocytes varied slightly or were unchanged during the one-year observation period. These results will be combined with those of other participating centres before being disseminated externally.

Assessment of the quality of red blood cell concentrates from young donors—a BEST study

Preclinical studies suggest that the post-donation recovery of red blood cells is reduced in donors presenting with iron deficiency. Given that young donors (aged 16 to 18) are at higher risk of iron deficiency, their red blood cell concentrates could be of inferior quality.

The objective of this multicentre project by the Biomedical Excellence for Safer Transfusion (BEST) group was to gain greater knowledge of the effect of the donor's age on the biology of red blood cells, the risk of iron deficiency, hemolysis, and immunomodulatory properties. Red blood cells from 25 donors aged 18 and 19 years, and 25 donors aged 55 years and over were collected and preserved for 42 days. Ferritin levels (representative of iron reserves) and hemolysis rates were compared between the two age groups. As expected, young women had lower ferritin levels than the other study groups. However, there was no difference in the hemolysis rates observed between the age groups. These results do not support the conclusion that age is a major factor for iron reserves and the quality of red blood cells. The results of other participating centres may make it possible to draw more specific conclusions.

Evaluation of the antibacterial and antiadhesive properties of a nanoparticulate coating for biomedical applications

An innovative strategy to prevent the survival and proliferation of bacteria in blood components is based on the application of an antibacterial and antiadhesive coating on the surface of biomedical devices.

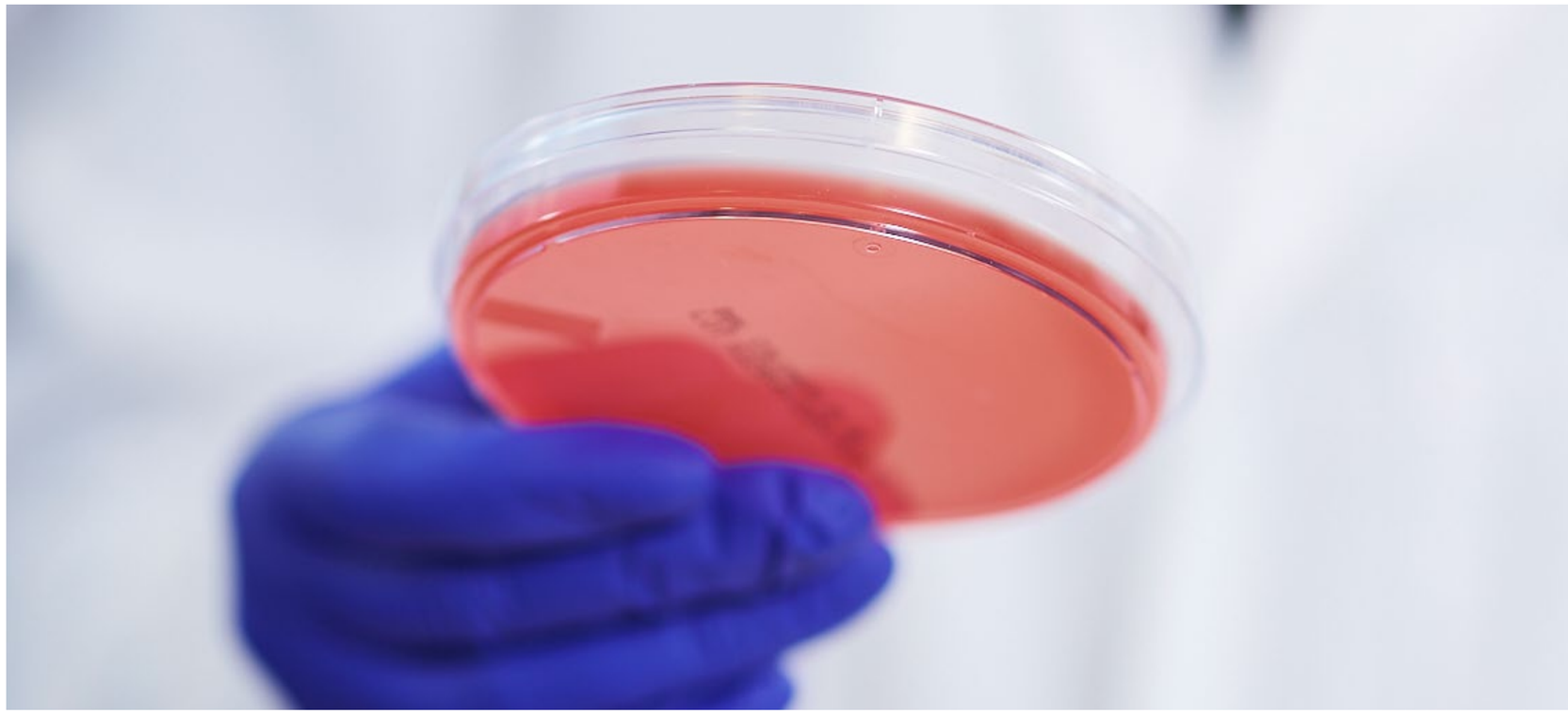
Once applied to the surface of biomedical devices, this new nanoparticular coating may reduce the risk of hospital-acquired infections or other infections associated with blood transfusion.

The objective of this project was to evaluate the antibacterial activity of such a coating (designed by Triphyll) once applied to the surface of polymeric materials, such as the PVC in the storage bags of blood products. The coating's physical and adherence qualities were characterized by optical and electron microscopy. Antibacterial activity was evaluated in compliance with the ISO 22196:2011 standard by testing bacterial species recognized for their potential pathogenicity. In the presence of the coating, the viability of two cell lines was estimated to be >90%, suggesting acceptable safety. The coating further demonstrated high antibacterial activity for all the bacterial strains examined. The results of this study suggest that applying the coating to the surface of biomedical devices could reduce the risk of hospital-acquired infections and other infections associated with the transfusion of blood products.

Impact of selection bias on epidemiological research: study of a specific case involving hyperemesis gravidarum and birth defects

In the absence of rigorous statistical controls, observational studies can be affected by selection bias, which can lead to incorrect results. Such bias could explain the protective association between hyperemesis gravidarum and birth defects, given that previous analyses did not take into consideration pregnancy terminations.

Using this association as a specific case, the objective of this study was to evaluate and estimate the incidence of selection bias related to the exclusion of high-risk groups from epidemiological research. A cohort of 2,115,581 viable births occurring in Canada between 1990 and 2016 was studied. In the uncorrected statistical models, hyperemesis gravidarum was associated with a 12% decrease in the risk of birth defects. This association disappeared or was even inverted when prenatal screening for birth defects and the chance of terminating a pregnancy were taken into account. These data, which were published in the journal Annals of Epidemiology, show the importance of considering several possible selection biases when conducting epidemiological studies.



Conducting studies planned to include missing data in epidemiological research

Modern analytical methods make it possible to increase the statistical power of a study while minimizing the random introduction of bias in the presence of missing data. One of these methods is to conduct studies planned to include missing data, making it possible to deliberately incorporate the missing data in an experimental design.

Such a design can be used by assigning 1) missing items to certain participants chosen randomly (multifaceted design), 2) missing measurement opportunities in a longitudinal design or 3) a recognized and costly baseline measurement (while other participants would be administered another less costly measurement). Although rarely used in epidemiology, these designs have been recommended for decades because of their many benefits, including a reduction in collection costs and in the burden imposed on participants, which could increase a study's validity. Héma-Québec published an article on the considerations, advantages and disadvantages related to this type of approach in the journal *International Journal of Epidemiology*.

SUPPORT TO OPERATIONS

The ultimate aim of many of the research activities conducted at Héma-Québec is to improve or optimize our operations in a concrete way.

Development of tests to measure the quality and efficacy of mother's milk

Necrotizing enterocolitis is an inflammatory intestinal condition that, if left untreated, can be fatal in premature infants. In addition to being a well-balanced nutritional source for newborns, mother's milk is one of the most effective approaches to preventing the condition. Currently, there is no test or marker to predict the ability of milk to prevent necrotizing enterocolitis. Only nutritional values and the absence of microbial contamination are typically used to evaluate the quality of the milk.

The main objective of this project is to develop a functional test and identify one or several biomarkers to predict the ability of mother's milk to prevent inflammation (one of the main characteristics of necrotizing enterocolitis). A functional test using intestinal cells highlighted the wide variability in the anti-inflammatory ability of various milk donations. Additional work is under way to identify biomarkers that can predict the anti-inflammatory ability of the milk.

Study of warming incidents involving cryopreserved hematopoietic stem cells

Cryopreserving cord blood stem cells makes it possible to maintain a public bank available worldwide to hematologist-oncologist transplant physicians who must perform a hematopoietic transplant on patients in need. While cryopreservation puts cells under significant stress, this process is necessary and optimized. The NetCord standard of the Foundation for the Accreditation of Cellular Therapy (FACT), to which our cord blood bank adheres, requires that warming incidents be minimized and documented.

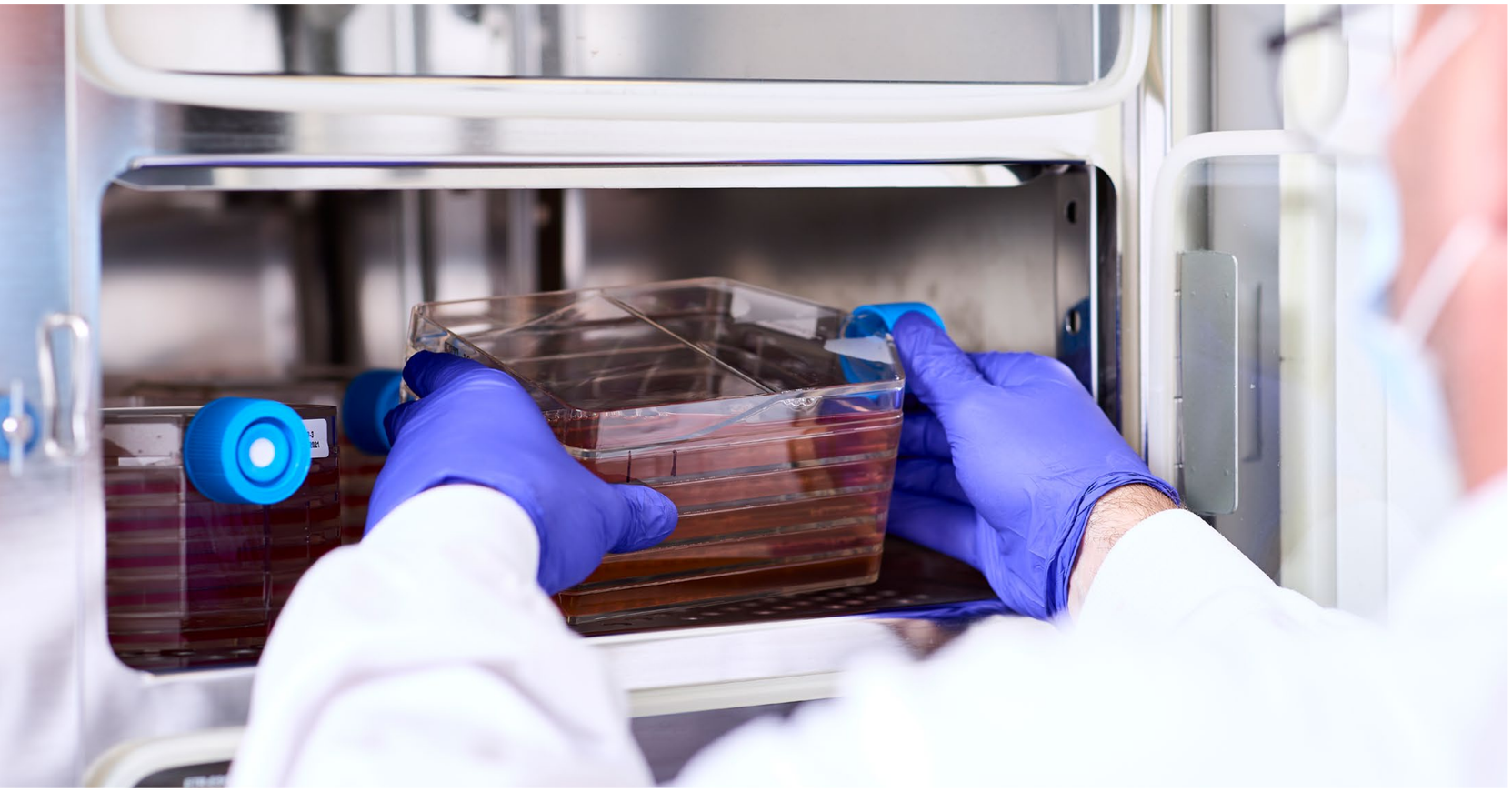
This project helped identify and characterize the warming incidents that are likely to occur in the Public Cord Blood Bank and quantify the impact of these incidents on the stem cells. We were able to produce a list of recommendations to improve cryogenic work practices at the Bank. These changes will be officially implemented in the next update and presented to the FACT auditors.

Optimization of the handling and cryopreservation procedure for autologous stem cell units

Autologous stem cells are used to treat cancer patients. The collection of these cells requires several steps, in particular the handling, cryopreservation, storage and distribution of the cells. These services are provided by Héma-Québec and some hospitals.

Ultimately, the optimization of the handling and cryopreservation procedure for autologous stem cell units will benefit all Héma-Québec's partners, especially those wishing to acquire the FACT accreditation.

To help one of its partners obtain the Foundation for the Accreditation of Cellular Therapy (FACT)—Hematopoietic Cellular Therapy accreditation, Héma-Québec is currently optimizing the treatment and cryopreservation of autologous stem cells. So far, all necessary regulatory changes have been identified in order to modify controlled documents and the computer system. This project will ultimately benefit all Héma-Québec's partners, especially those wishing to acquire this accreditation.



Processing of hematopoietic stem cells to improve engraftment

Patients with hematologic malignancies or certain blood disorders can be treated with a hematopoietic stem cell (HSC) transplant. Cord blood is a recognized transplant alternative for HSC patients but has the disadvantage of containing a low number of HSC, which has historically restricted its use in pediatric patients.

The processing of CD34+ hematopoietic stem cells (HSC) using a platelet lysate may be a beneficial strategy to improve clinical outcomes following an HSC transplant.

The aim of this project was to evaluate the effect of processing HSC using a platelet lysate. This approach could make it possible for CD34+ HSC from cord blood to migrate more efficiently to the bone marrow following transplantation and foster their retention at this location. Results show that this processing increases by almost three folds the abundance of CD34 on the surface of the HSC. Moreover, the migration of these cells as a function of the concentration gradient of rhSDF-1 (chemokine) is almost seven times more effective in an *in vitro* assay. Finally, injecting processed HSC directly into the bone marrow of immunodeficient mice significantly improved engraftment. Processing CD34+ HSC with a platelet lysate could, therefore, be a beneficial strategy to improve the clinical results following an HSC transplant.

Optimization of the capacity of the storage room for stem cell cryo-containers

Héma-Québec's stem cell bank was established in 2008. Two types of products are stored there: cord blood products for the worldwide cord blood bank, and autologous peripheral stem cells.

To meet the growing demand of hospitals, this project aimed to optimize the storage capacity of the room where the cryo-containers holding the cryopreserved stem cells were stored. More specifically, the objective was to add 12 cryo-containers to the room. To date, the removal of expired cryo-containers and the relocation of furniture has helped reach one third of the targeted goal. Other steps are under way to maximize the optimization of the remaining space and fully achieve the objective.

Evaluation of the bactericidal potential of a brief incubation at 35°C of ocular tissues in Optisol-GS

Incubation of corneas at 35°C in a preservative medium (Optisol-GS) could improve the precision of quality control tests and the efficacy of the antibiotics contained in the solution. These advantages could help reduce the bacterial load and rejection rate of the corneas.

The objective of this project was to evaluate the bactericidal effect of a brief incubation (0-4 hrs) of the corneas in a preservative medium maintained at 35°C. In the first phase of the project, the most frequent contaminants (*Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus faecalis* and *Candida albicans*) were added to the solution. Exposure at 35°C resulted in a significant decrease in bacterial concentrations compared with incubation at 4°C. In the second phase, the normal bacterial flora of nine pairs of corneas was studied, and the impact of exposure at 35°C on the flora was evaluated. Most bacteria found on the corneas were acceptable since they belonged to species usually found on the skin, but one sample contained *Escherichia coli*, which is not considered acceptable for the production of ocular tissues. None of the nine corneas handled and preserved at 35°C showed any bacterial growth, while two of the nine corneas (22%) stored at 4°C showed such growth. Among the corneas preserved at 4°C, the bacterial species found were *S epidermidis* and *P granulosum* (two bacteria considered acceptable), while there was no longer any trace of *E coli* in the contaminated chamber. This study shows that a brief exposure to a preservative medium maintained at 35°C significantly improves the disinfection of ocular tissues.

This study demonstrates that a brief exposure to a preservative medium maintained at 35°C significantly improves the disinfection of ocular tissues.

Evaluation of a supercritical CO_2 treatment to clean and sterilize cancellous bones and tendons

Allografts of musculoskeletal tissues (cancellous bones, cortical bones, tendons) are used, among other things, in orthopedic and dental surgery. The mission of Héma-Québec's Human Tissue Bank is to harvest tissues from cadavers while maintaining the greatest respect for the donors. The tissues are then treated, cleaned, packaged and decontaminated. The use of supercritical CO_2 ($scCO_2$) is an alternative to conventional cleaning and sterilization techniques. $scCO_2$ can permeate complex structures and porous materials and solubilize certain substances, such as fat and blood, to clean the tissues. $scCO_2$, to which additives are added, also has antimicrobial properties.

The objective of this project was to evaluate the efficacy of treatment with $scCO_2$ for the cleaning and terminal sterilization of cancellous bones and tendons. Results show that treatment with $scCO_2$ is effective in cleaning cancellous bones and decreases the bacterial load and the quantity of lipids and proteins. In the presence of hydrogen peroxide and peracetic acid, $scCO_2$ properly sterilizes the tendons and cancellous bones by decreasing the bacterial load of six logs (spore-forming bacteria). Moreover, residues from the cleaning and sterilization of the cancellous bones with $scCO_2$ in the presence of these additives had no cytotoxic effect. Results related to cytotoxicity are still awaited for tendons. Eventually, the biomechanical properties of tendons treated with $scCO_2$ will be compared with those of tendons treated with the current method, irradiation.

Evaluation of the impact of cannabis consumption on the quality of blood products

The current regulation does not require a minimum waiting period for donating blood after consuming cannabis. The cognitive ability of donors (i.e., ability to understand the consent form and qualification questionnaire) is the only factor taken into consideration when donating. Concentrations of cannabinoids, including tetrahydrocannabinol (THC) and cannabidiol (CBD), vary greatly from one product consumed to another, which could influence the quality of the blood cells collected.

The main objective of this project was to determine the impact of cannabinoids on the quality of blood products. To date, the effect of THC on the preservation of red blood cells and on platelet aggregation was tested. Preliminary results show a significant increase in free hemoglobin (a sign of hemolysis) in the packed red blood cells produced from whole blood exposed to THC. Furthermore, THC seems to significantly reduce the aggregation ability of platelets isolated from blood. Testing of the effects of CBD and of a mix of cannabinoids (more representative of cannabis consumed) are currently under way.

Impact of wait time on platelet products in a bacterial viability assayer

Because of the wait time between the collection and culture test performed on platelet samples, some harmful bacteria might survive and not be detected by the culture test, which could compromise the safety of the final product.

The aim of the project was to determine if the bacteria present in a platelet concentrate could survive when the sample was temporarily stored in an assayer before undergoing testing in an automated microbial detection system. Three assayer sizes (10 ml, 20 ml, and 35 ml) were filled with a platelet concentrate inoculated with one of the five strains of bacteria tested (*Bacillus cereus, Staphylococcus aureus, Klebsiella pneumoniae, Clostridium perfringens* and *Escherichia coli*). Samples were then collected after 0, 12 and 24 hours; one bag of platelet concentrate inoculated with one of the five strains continued to be stirred as a positive control. After 12 hours, the *B cereus, S aureus* and *E coli* concentrates in the control bags were similar to those in the samples that had passed through the three sizes of assayer. In the case of *C perfringens*, a slight decrease in the bacterial concentration was observed with each size of assayer. After 24 hours, a notable growth was observed for *E coli, S aureus, K pneumoniae* and *C perfringens* with the three sizes of assayer. The concentrations of *B cereus* samples that passed through the assayers were similar to those in the control bags after 24 hours, regardless of the size of the assayer tested. In summary, the five representative bacterial strains of contaminants typically found in platelet concentrates survived in the assayers for 24 hours.

Multicentre study of the release of HMGB1, CD40L and CD62P during the storage of platelet concentrates

While generally safe, transfusions of platelets sometimes cause severe adverse reactions (SAR). These SAR may be linked (at least in part) to the immunomodulatory properties of the platelets activated while in storage. During this activation, the CD62P protein is transferred to the surface of the plasma membrane of the platelets and released with CD40L and HMGB1, which are both implicated in SAR.

The objective of this international study was to examine the release of soluble HMGB1, CD40L and CD62P in platelet concentrates prepared and stored using different processes. More than 3,500 supernatants of platelet concentrates were collected, and the levels of soluble HMGB1, CD40L and CD62P were evaluated. Shortly after storage, the concentrations of soluble HMGB1, CD40L and CD62P remained similar regardless of the storage solution (plasma or additive solution for platelets) and storage temperature used. However, in the samples stored longer, levels of soluble HMGB1 varied greatly based on the type of platelets (e.g., apheresis), the storage solution and the storage conditions (e.g., temperature). Interestingly, soluble HMGB1 had a release profile that was different from that of soluble CD62P and CD40L in response to various stresses related to the preparation process of platelet concentrates. The release mechanisms for soluble HMGB1 could, therefore, be different than those of soluble CD62P and CD40L. These data highlight the importance of the steps involved in the production and storage of platelet concentrates. Other studies are needed to understand the potential clinical impact of these variations.

Prediction of the rate of return of young blood donors

Several factors can influence a donor's decision to give blood on a recurrent basis. Identifying these factors in young donors is especially important to put in place measures to renew the donor pool.

The aim of this study was to predict the frequency of donations by young donors using a statistical model based on machine learning. The population analyzed included more than 80,000 donors between the ages of 18 and 24. In the end, the model correctly predicted the frequency of donations in 91% of the cases. The major factors that seemed to predict the frequency of donations were the number of attempts to contact the donor, the age of the donor, the number of adverse reactions experienced following earlier donations, and the marital status and ethnic group of the donor. These results, which were published in the journal ISBT Science Series, help better understand the behaviour of donors and could improve the efficacy of initiatives under way to retain young donors.

Installation of a new automated device to identify antibodies and red blood cell phenotypes

Various immunohematological tests are routinely performed to screen for antibodies to different blood group antigens and to characterize blood groups (phenotypes). Typically, red cell antibodies and phenotypes are determined using manual "tube" and "gel" techniques based on the principle of red blood cell agglutination.

The Echo Lumena system is an instrument based on the solid phase extraction principle designed to perform fully automated tests. A plan to evaluate the instrument was drawn up to determine performance acceptance criteria, test methods and verification data. The performance tests showed that the instrument produces results consistent with expectations. This new instrument was, therefore, validated and installed as a complementary technique to existing ones in our laboratories to better exploit the various technologies available and produce the most accurate results possible.

Evaluation of the non-destructive sampling technology developed by Canadian Blood Services to control the quality of packed red blood cells

To avoid sampling donations for quality control and to reduce losses of blood components and costs associated with these losses, Canadian Blood Services developed a non-destructive sampling method for blood products.

The main objective of this project was to evaluate the performance of this technology in controlling the quality of packed red blood cells. The metabolic behaviour of the samples collected in sample bags was monitored during the storage period and compared with that of the initial bags for each of the processes used to prepare the packed red blood cells. The study showed that the behaviour of the sample bags of packed red blood cells closely resembled that of the initial bags for most quality markers, especially those measuring storage lesions.

Testing the growth ability of bacterial strains that are relevant for the transfusion of platelet concentrates using bioballs

The use of lyophilized BioBall® (bioMérieux) bacterial reference strains is being studied in different laboratories as an alternative to suspended traditional strains for growth validation testing of platelet concentrates.

In this study launched by the Working Party on Transfusion Transmitted Infectious Disease (WP-TTID) of the International Society of Blood Transfusion (ISBT), Héma-Québec used bioballs containing precisely 30 colony-forming units (CFU) of *Klebsiella pneumoniae* or *Staphylococcus aureus* to inoculate platelet concentrates obtained through the Reveos® process on day 1 following collection. The growth kinetics were evaluated at days 1, 2, 3, 4 and 7, following collection. Bacterial growth was detected in all the platelet concentrates in a reproducible manner with the two contaminating strains. Thirty CFU were detected starting on day 2 for *K pneumoniae*, and growth plateaued on day 3. In the case of *S aureus*, 30 CFU were detected on day 3, and growth plateaued on day 4. In summary, bioballs are simple to use and maintain since they are lyophilized and contain precise quantities of contaminants. In the wake of the results of this interlaboratory study, bioballs could facilitate and standardize growth validation tests.

Bacterial growth in cold platelets

In September 2019, the Food and Drug Administration granted an exemption allowing the storage of platelet concentrates at 1-6°C for up to 14 days without stirring. These storage conditions could be beneficial compared with standard conditions (20-24 °C) because of the superior hemostatic function of this blood product. Unfortunately, the rare studies that focused on the safety of these conditions did not include psychrotrophic bacteria or seeded too great a quantity of bacteria to adequately represent normal bacterial contamination.

In this multicentre international study by the Working Party on Transfusion Transmitted Infectious Disease (WP-TTID) of the International Society of Blood Transfusion (ISBT), in which Héma-Québec participated, bacterial growth produced in platelet concentrates stored at 1-6°C was compared with that produced in concentrates stored at 20-24°C (standard conditions). Five transfusion-relevant bacterial strains, including some psychrotrophic strains, were used for dosing tests. In the end, all the bacterial strains used in the study proliferated in the platelet concentrates stored at 20-24°C, while only the psychrotrophic strains showed a certain level of proliferation in the concentrates stored 1-6 °C. In summary, while there may be some advantages to storing platelet concentrates at 1-6 °C (e.g., increase in storage time and limitation of the growth of several bacterial species), psychrotrophic bacteria remain a safety issue for recipients.

Other support to operations

- To replace OS91 infrared thermometers manufactured by OMEGA, the performance of new infrared thermometers (62 MAX+ by Fluke) was evaluated. In the end, these new thermometers showed a temperature difference of ≤1°C compared with the reference thermometers under all conditions evaluated and are, therefore, compliant.
- A visual inspection guide was prepared to assist in the interpretation of observations related to plasmapheresis.

OUTREACH

The year 2020-2021, marked by the COVID-19 health crisis, had a major impact on the external scientific outreach of the organization. Forty-one peer-reviewed publications were posted online or published in a print version during the year. Outreach through guest lectures and papers presented at conferences was also significant. The scientific and medical staff were invited to present 10 guest lectures. Six oral presentations and 10 posters were presented during national and international conferences. Finally, the scientific and medical staff facilitated a workshop as part of an international conference.

Regarding intellectual property, the year 2020-2021 achieved major milestones in the quest for patent applications for a stem cell culture invention that combines the effect of mild hyperthermia and pyrimido-indole compounds. During the past year, patents for this invention were issued to Australia, the United States, Europe (validated in Germany, France and the United Kingdom), and Singapore. The issuance of these patents confirms the validity of this invention and consolidates Héma-Québec's position in efforts to enhance the value of this intellectual property.

In addition, the Office of the Vice-President, Medical Affairs and Innovation reaches out internally through the dissemination of operational test reports. Stemming from projects linked to the organization's various product lines, these reports present the results of studies on the optimization of processes or tests of new equipment and technologies. Eighteen internal reports were produced during 2020-2021. The conclusions of these reports have often had direct benefits for operations and the supply of products destined for hospital clients.

EXTERNAL OUTREACH

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Guest lectures, papers presented at conferences, workshop facilitations

Canadian Society for Transfusion Medicine (CSTM) Research Day (virtual event), May 27, 2020

Guest lecture

Fernandes MJ, Girard M, Murru A. « Assessment of the quality of granulocyte concentrates to optimize their use in transfusion therapy. »

Cell Therapy Transplant Canada (CTTC) 2020 Annual Conference (virtual event), August 5, 2020

Oral presentation

Boccacci Y, Margaillan G, Dumont N, Drouin M, Doyon Y, Laganière J. « Maturation of ex vivo cultured human erythrocytes and sickle cell disease modelling using CRISPR-CAS9. »

ISEH 2020 Virtual Scientific Meeting (virtual event) August 19–21, 2020

Poster

Boccacci Y, Margaillan G, Dumont N, Drouin M, Doyon Y, Laganière J. « Maturation of ex vivo cultured human erythrocytes and sickle cell disease modelling using CRISPR-CAS9. »

Cord Blood Connect 2020 Virtual International Congress (virtual event), September 10–17, 2020

Guest lectures

Fournier D. « The quest toward a rapid, robust and validated stem cell potency assay. »

Trépanier P. « An update on our quest toward a rapid, robust and validated stem cell potency assay. »

Solidarity II Collaborators' Meeting (virtual evet)

Conférences sur invitation

Bazin R. « Waning of SARS-CoV-2 RBD antibodies in longitudinal convalescent plasma samples within four months after symptom onset. » Delivered on September 18, 2020.

Bazin R. « Waning of SARS-CoV-2 RBD antibodies in longitudinal convalescent plasma samples within four months after symptom onset: An update. » Delivered on October 30, 2020.

Foundation for the Accreditation of Cellular Therapy (FACT) Virtual Inspection and Accreditation Workshop (virtual event) September 21, 2020

Guest lecture

Fournier D, D'Avanzo B. « A guided tour of a FACT-accredited cord blood bank: Identification of deficiencies and discussion. »

8th Day of the Department of Molecular Medicine (virtual event) October 13, 2020

Oral presentation

Fonseca S, Cayer MP, Ahmmed KMT, Khadem-Mohtaram N, Brouard D. « Caractérisation de l'activité antibactérienne d'un revêtement à base de nanoparticules de SiO2 pour prévenir la contamination de produits sanguins. »

AABB 2020 Virtual Annual Meeting (virtual event) October 3–5, 2020

Posters

Arsenault V, Yan MTS, Tait G, Lewin A, Pendergrast J. « Learnserology.ca: An online educational resource for post-graduate hematology trainees. »

Boyer L, Dussault N, Trépanier P, Brouard D, Fournier D. « Shock tolerance of cyropreserved peripheral blood stem cell freezing bags during transport. »

de Grandmont MJ, Cayer MP, Djaileb A, Live L, Pelletier J, Masson JF, Broudreau D, Brouard D. « Development of a point-of-care serological test for the detection of SARS-CoV-2 specific antibodies in human plasma or serum by surface plasmon resonance. »

Fonseca S, Cayer MP, Ahmmed KMT, Khadem-Mohtaram N, Brouard D. « Characterization of the antibacterial activity of a SiO2 nanoparticle coating to prevent bacterial contamination in blood products. »

Laforce-Lavoie A, de Grandmont MJ, Nolin MÈ, Padmavathy L, Brouard D. « The contact shock freezer technology for plasma processing in collection centers. »

Workshop

Lewin A, Tiberghien P, Shinar E, O'Brien SF. « Men who have sex with men: Is plasma donation the next step? »

7th Annual Canadian Haemoglobinopathy Association Conference (virtual event), October 24, 2020

Guest lecture

Robitaille N. « Utilization of blood resources in a crisis »

Thalassemia Patient & Parent Education Series, Québec Session (virtual event), October 31, 2020

Guest lecture

Robitaille N. « Utilization of blood resources in a crisis: Approach of blood bank »

Bio-Rad Immunohematology Webinar (virtual event) November 10, 2020

Guest lecture

Baillargeon N. « Antibody identification : Technique and Reagents »

23rd Annual Chemistry and Biochemistry Graduate Research Conference (CBGRC) (virtual event), November 20, 2020

Oral presentation

Fonseca S, Cayer MP, Ahmmed KMT, Khadem-Mohtaram N, Brouard D. « Characterization of the antibacterial activity of a SiO2 nanoparticle coating to prevent bacterial contamination in blood products. »

Recertification of the Association des bénévoles du don de sang (ABDS) Ambassadeurs/Mentors (virtual event) November 27, 2020

Guest lecture

Baillargeon N, Joron S. « Projet d'étude de population auprès des Premières Nations »

Immucor Virtual Education Day (virtual event) December 2, 2020

Guest lecture

Baillargeon N. « Agglutination et adhérence: Qu'est-ce qu'on y voit? »

ISBT 2020 Virtual Congress (virtual event) December 12–16, 2020

Oral presentations

Houle-Aubé É, Lewin A, Grégoire Y, O'Brien S, Custer B, Seed C, Steele W, Pillonel J, Davison K, Germain M, Arsenault C, Camirand Lemyre F. « Apheresis plasma deferral criteria for men who have sex with men and HIV residual risk: A stochastic simulation. »

Lewin A, Delage G, Grégoire Y, Germain M. « Trends in vasovagal reactions in blood donors and impact of provincial mitigation interventions: A 4-year retrospective study with interrupted time-series analysis. »

Cloutier M, Gasser R, Prévost J, Fink C, Ducas É, Ding S, Dussault N, Landry P, Tremblay T, Laforce-Lajoie A, Lewin A, Beaudoin-Bussières G, Laumaea A, Medjahed H, Larochelle C, Richard J, Dekaban G, Dikeakos J, Bazin R, Finzi A. « Major role of IgM in the neutralizing activity of convalescent plasma against SARS-CoV-2. »

Posters

Anand S, Prévost J, Richard J, Perreault J, Tremblay T, Drouin M, Fournier M, Lewin A, Bazin R, Finzi A. « Longitudinal analysis of the persistence of antibodies targeting the SARS-CoV-2 Spike in the plasma from convalescent donors. »

Beaudoin-Bussières G, Laumaea A, Anand S, Prévost J, Gasser R, Goyette G, Medjahed H, Perreault J, Tremblay T, Lewin A, Gokool L, Morrisseau M, Bégin P, Tremblay C, Martel-Laferrière V, Kaufmann D, Richard J, Bazin R, Finzi A. « Decline of humoral responses against SARS-CoV-2 Spike in convalescent individuals. »

Bres V, Proctor M, Self D, Gurrola A, Anderson G, Tonnetti L, Delage G, Lewin A, Kessler D, Stramer S, Linnen J. « Preliminary performance characteristics of a Plasmodium nucleic acid test on a fully automated system. »

Prévost J, Gasser R, Beaudoin-Bussières G, Richard J, Duerr R, Laumaea A, Anand S, Goyette G, Benlarbi M, Ding S, Medjahed H, Lewin A, Perreault J, Tremblay T, Gendron-Lepage G, Gauthier N, Carrier M, Marcoux D, Piché A, Lavoie M, Benoît A, Loungnarath V, Brochu G, Haddad É, Stacey H, Miller M, Desforges M, Talbot P, Gould Maule G, Côté M, Therrien C, Serhir B, Bazin R, Roger M, Finzi A. « Cross-sectional evaluation of humoral responses against SARS-CoV-2 Spike. »

Patents issued during 2020-2021 and patent applications pending

Methods for culturing and/or differentiating hematopoietic stem cells into progenitors and uses thereof. Patents issued in Australia (AU2016273439B2), the United States (US10828329B2), Europe (EP3303570B1; validated in Germany, France and the United Kingdom and Singapore (SG11201710067U).

Patent applications under review in Canada (published under CA2987974A1), China (published under CN107922926A), the Republic of Korea (published under KR20180023947A), the United States (divisional application published under US2021023131A1), Israel (published under IL256093), Japan (published under JP2018516089A) and New Zealand (published under NZ738216). Laganière J, Dumont N, inventors. Héma-Québec, assignee. Patent expiry: 06-03-2036.

INTERNAL REPORTS

Dussault N, Lewin A, Cloutier M. Utilisation des thermomètres infrarouges en collecte (GEO-111 2020H/33064). Final report presented to Patrice Desgagné (Office of the Vice-President, Blood Products and Mother's Milk), June 1, 2020.

Dussault N, Robidoux J, Lewin A, Cloutier M. Évaluation de l'utilisation de thermomètres infrarouges pour la table d'accès sur les collectes et les centres de donneurs (GEO-111 2020H/33064). Final report presented to Patrice Desgagné (Office of the Vice-President, Blood Products and Mother's Milk), June 1, 2020.

Brouard D. NC-004219, Variation de la température de produits sanguins en fonction de celle observée pour la solution de la sonde de température. Final report presented to Martin Paquette (Office of the Vice-President, Blood Products and Mother's Milk), July 7, 2020.

de Grandmont MJ, Cayer MP, Brouard D. Investigation CAPA-19-0035 (GEO-147B/33240). Final report presented to Guylaine Benoit (Office of the Vice-President, Blood Products and Mother's Milk), July 14, 2020.

Ducas É, Landry P, de Grandmont MJ, Cloutier M. Évaluation de l'efficacité d'un chambrage à 35 °C des tissus oculaires sur la réduction de la charge bactérienne (GEO-177/33345). Final report presented to Étienne Fissette (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), July 22, 2020.

Fournier MJ, Landry P, Cloutier M. Souches bactériennes de référence pour les culots globulaires: étude multicentrique du sous-groupe de travail sur les maladies transmissibles par transfusion de l'ISBT (GEO-162). Final report presented to à Gilles Delage (Office of the Vice-President, Medical Affairs and Innovation), July 22, 2020.

Laforce-Lavoie A, Ducas É, de Grandmont MJ, Cloutier M. Épaisseur des tissus cutanés (TCU) : utilisation de lasers à réflexion diffuse (GEO-158/33208). Final report presented to Étienne Fissette (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), July 23, 2020.

Nolin MÈ, Laforce-Lavoie A, de Grandmont MJ, Brouard D. Évaluation de la technologie de congélateur contact pour le traitement de plasma dédié au fractionnement (GEO-170/33305). Final report presented to Annie Blackburn (Office of the Vice-President, Blood Products and Mother's Milk), August 28, 2020.

Boyer L, Dussault N, Girard M. Caractérisation des constituants sanguins résiduels dans les réservoirs de retour des cassettes Trima Accel (GEO-183/33421). Final report presented to Caroline Masse (Office of the Vice-President, Blood Products and Mother's Milk) and Renée Bazin (Office of the Vice-President, Medical Affairs and Innovation), September 23, 2020.

Robidoux J, Drouin F, Girard M. Vérification de l'étanchéité des scellements des pochettes externes des tissus musculosquelettiques lyophilisés (RLPR568). Rapport 4: essais d'humidité résiduelle sur des pochettes présentant un scellement irrégulier (GEO111_2019U/33064). Final report presented to Ève Lamontagne (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), October 1, 2020.

Boyer L, Dussault N, Brouard D. Caractérisation des bris observés au niveau des dispositifs de cellules souches périphériques cryopréservées (GEO-111 (2019H)/33064). Final report presented to Diane Fournier (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), October 8, 2020.

Robidoux J, Nolin MÈ, Brouard D. Caractérisation des propriétés physiques de la pâte d'os et identification de marqueurs qualité potentiels pour le produit en développement. Phase I, preuve de concept: évaluation de la plasticité de la pâte d'os par mesure de résistance à l'écoulement (GEO-111/2020D). Final report presented to Étienne Fissette (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), October 8, 2020.

Laflamme G, Paré I, Dumont N, Rouleau P, Tremblay-Desbiens C, Loubaki L, Rapport sur l'évaluation de différents tests d'ostéoinduction pour l'os déminéralisé (INNOV-33383). Final report presented to final Étienne Fissette (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), October 9, 2020.

Laforce-Lavoie A, de Grandmont MJ, Brouard D. Agitation automatisée des culots globulaires : évaluation du Wave Action Rotator (Fisher Scientific) (GEO-111/2020B). Final report presented to Omar Bouktrane (Project Management and Continuous Improvement Division, Office of the Vice-President, Quality and Development), October 16, 2020.

Ducas É, Landry P, Cloutier M. Essais opérationnels et de performance de l'incubateur IMC18 (GEO-177/33345). Final report presented to Étienne Fissette (Human Tissue Operations, Office of the Vice-President, Medical Affairs and Innovation), December 2, 2020.

Dussault N, de Grandmont MJ, Brouard D. Évaluation des changements apportés par la migration vers Trima v7.0 dans un contexte opérationnel à Héma-Québec. Final report presented to Synthia Sauvageau (Office of the Vice-President, Blood Products and Mother's Milk), December 4, 2020.

Robidoux J, de Grandmont MJ, Brouard D. Évaluation des impacts opérationnels liés au changement des thermoscelleuses multi-têtes et à la préparation des segments (GEO-111-2020M/33064). Final report presented to Pierre Noël (Office of the Vice-President, Blood Products and Mother's Milk), January 22, 2021.

Trépanier P, Rhéaume MÈ. Caractérisation des événements de réchauffement du sang de cordon (AMI-1916/33428). Final report presented to Diane Fournier (Stem Cell Division, Office of the Vice-President, Transfusion Medicine), March 10, 2021.

Dussault N, Brouard D, de Grandmont MJ. Évaluation de performance et établissement des limites instrumentales du thermomètre infrarouge 62MAX+ proposé par la compagnie FLUKE (AMI-2107/33500). Final report presented to Cynthia Runz (Infrastructure and Industrial Safety Division, Office of the Vice-President, Finance and Infrastructure), March 16, 2021.

TRAINING

Training of college and university students, post-doctoral interns and Fellows

Since its founding, Héma-Québec has contributed to training the next generation of specialists in basic and applied research in fields that are relevant to its activities. Our organization also regularly welcomes clinicians who wish to acquire a specialization in transfusion medicine. Beyond 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 the year 2020-2021, the scientific staff of the Medical Affairs and Innovation Department codirected the work of six master's students and one doctoral student enrolled at the Université Laval. Four interns pursued a post-doctoral internship in Medical Affairs and Innovation during the same period. Two undergraduate students enrolled at the Université Laval completed an internship in the research laboratories of our Quebec City facility during summer 2020. Finally, the Office of the Vice-President, Transfusion Medicine welcomed three Fellows who came to take part in training internships in transfusion medicine.

Contribution of Héma-Québec's scientific staff to its training activities and continuing education workshops

In addition to training initiatives for its own staff, Héma-Québec contributes to maintaining the highest quality standards by producing educational material for its hospital partners. For several years, Héma-Québec has offered training in immunohematology (both theoretical and practical) to laboratory technicians working in hospital blood banks in Québec and elsewhere in the world (Web educational platform). The aim of this training, offered in three languages (French, English and Spanish), is to enable technicians to acquire the methodology and techniques needed to solve immunological problems encountered on a daily basis in a blood bank laboratory, as well as problems encountered during serological studies in patients suffering from autoimmune hemolytic anemia (see the website for more details). This past year, 145 registrations were recorded for this training, funded by Grifols.

In collaboration with the Leukemia & Lymphoma Society of Canada (LLSC), Héma-Québec developed a two-hour training program on hematopoietic stem cells and on transfusion products for patients with hematopoietic cancers. The training focuses on the interference of certain treatments on HLA-compatible blood cells and platelets, the stem cell registry and various stem-cell-based products (e.g., cord blood and peripheral stem cells). This training is recognized by the Université de Montréal's Faculty of Nursing and by the Ordre professionnel des technologistes médicaux du Québec (OPTMQ). In all, 206 participants were enrolled in this training in 2020.

Héma-Québec also provides regulatory training aiming to ensure that the staff that collect cord blood in partner hospitals are properly trained and qualified. In the past year, 132 registrations of physicians and nurses were recorded for this training.

Finally, Héma-Québec's Public Cord Blood Bank is proud to have collaborated with the Banque de sang de cordon de Liège and the Foundation for the Accreditation of Cellular Therapy (FACT) on the presentation of a webinar on cord blood in support of World Cord Blood Day. The objective of this webinar was to discuss current progress in the use of UM171-expanded cord blood transplantation and to understand the effect of the COVID-19 pandemic on cord blood collection and transplantation in France. In all, 211 participants enrolled in the 2020 edition of this webinar, which was freely accessible online.

3
FELLOWS IN TRANSFUSION MEDICINE

4
POST-DOCTORAL FELLOWS

1
DOCTORAL STUDENT

6
MASTER'S STUDENTS

2
UNDERGRADUATE STUDENTS

694
REGISTRATIONS TO VARIOUS TRAINING SESSIONS OFFERED BY THE SCIENTIFIC STAFF

RESEARCH PARTNERS

Héma-Québec benefits from the expertise of its many partners who collaborate on several of its research activities. We would especially like to thank the partners listed below for their close collaborations during the year 2020-2021.

- **Affinité Instruments:** Affinité Instruments is a pioneer in the development and marketing of new technologies that use surface plasmon resonance (SPR). In the past year, Héma-Québec collaborated with the company on the development of an SPR technology to detect antibodies to SARS-CoV-2 (see page 11) as well as on IgA dosing and the identification of donors whose plasma is IgA-deficient (see page 13).
- **Public Health Agency of Canada (PHAC):** PHAC promotes and protects the health of Canadians through leadership, partnership, innovation and action in public health. This agency was a key partner in a study aiming to evaluate the diversity of anti-SARS-CoV-2 assays use by blood banks as part of seroprevalence studies (see page 12) and the establishment of a biobank of samples from frequent plasma donors (PlasCov).
- **Banque de sang de cordon de Liège:** This blood bank is a major partner with whom we share many missions, values and standards of excellence. In the past year, Héma-Québec joined the Banque de sang de Liège to present a webinar on cord blood (see page 28).
- **Biomedical Excellence for Safer Transfusion (BEST):** BEST is an international consortium of blood product suppliers and university and industrial experts who document and formulate recommendations on the procedures to follow to improve operational and clinical practices in transfusion medicine and cell therapy. In 2020-2021, Héma-Québec participated in several collaborations with the BEST group, including a study aiming to compare the prevalence and incidence of HIV between donors from various countries, States or provinces and the general public (see page 8), an in-depth study of lymphopenia in frequent platelet donors (see page 15), and an evaluation of the quality of red blood cell concentrates from young blood donors (see page 15).
- **Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM):** The CRCHUM is a research hub that brings together experienced scientists from various fields involved in the improvement of health. The CRCHUM covers a vast spectrum of activities, from basic research to clinical research. In the past year, the CRCHUM has been a major partner in the following projects: CONCOR-1 and REMAP-CAP studies (see page 6), the characterization of the role of various classes of antibodies to SARS-CoV-2 (see page 11), and the characterization of the longevity of the humoral response to SARS-CoV-2 (see page 11).
- **Centre hospitalier de l'Université de Montréal (CHUM):** The CHUM is an innovative health facility providing specialized and super specialized services to adult patients in Québec. The CHUM was a key partner in a study to identify fetal *RHD* genotype using a blood sample (see page 14).
- **Centre hospitalier universitaire (CHU) Sainte-Justine:** The CHU Sainte-Justine is a health facility that, in addition to fulfilling its mission of providing healthcare to Québec children, youth and mothers, is home to high-level research activities. Héma-Québec was able to count on collaboration with the CHU Sainte-Justine on a project to identify fetal *RHD* genotype (see page 14).
- **ExCellThera:** ExCellThera is a molecular medicine company specializing in the development of molecular tools to expand the number of hematopoietic stem cells (HSC) and improve the efficacy of HSC transplants. In anticipation of a clinical study on the ECT-001 technology, the company developed an algorithm capable of identifying the HLA profiles of cord blood that were most likely to be compatible with recipients. Héma-Québec is proud to have helped ExCellThera to test this algorithm under real conditions (see page 12).
- **Foundation for the Accreditation of Cellular Therapy (FACT):** FACT promotes advances in cell therapy and regenerative medicine by accrediting healthcare institutions that have shown exemplary cell therapy practices. Héma-Québec collaborated with the FACT to develop a webinar on cord blood (see page 28).
- **Grifols** is a leader in the marketing of plasma protein-based products, instruments and other products for hospitals and blood bank laboratories. Héma-Québec wishes to thank Grifols for its support to the immunohematology training offered by our organization (see page 28).
- **Groupe de travail sur l'immunité face à la COVID-19 (GTIC):** The GTIC is a working group formed in response to COVID-19, which brings together clinical experts whose mandate is to determine the extent of SARS-CoV-2 infection in Canada, understand the nature of immunity following SARS-CoV-2 infection, develop improved antibody testing methods and monitor scientific developments in vaccines. Héma-Québec collaborated closely with the GTIC in a study of the role of various classes of antibodies in immunity to COVID-19 (see page 11) the prevalence of SARS-CoV-2 in Québec (see page 6), the international comparison of anti-SARS-CoV-2 assays (see page 12), and the persistence of the humoral response to SARS-CoV-2 over time (see page 11).

- **Institut national de santé publique du Québec (INSPQ) and the ministère de la Santé et des Services sociaux (MSSS):** The INSPQ is a centre of public health expertise. Its mission is to advance knowledge and formulate strategies aiming to improve the health and well-being of Quebecers. The MSSS provides health and social services to Quebecers to improve the health and well-being of its citizens. In response to the COVID-19 pandemic, Héma-Québec conducted a seroprevalence study to inform the INSPQ and the MSSS about the seroprevalence of anti-SARS-CoV-2 in the Québec population (see page 6).
- **International Society of Blood Transfusion (ISBT):** ISBT promotes the sharing of knowledge about transfusion medicine and provides professionals in the field with educational resources to optimize their clinical practice. During the year 2020-2021, Héma-Québec collaborated with ISBT working groups to complete a variety of projects, including the use of bioballs in bacterial growth tests (see page 22) and a study of bacterial growth in cryopreserved platelets (see page 22).
- **Canadian Blood Services (CBS):** CBS is the supplier of blood products outside of Québec. Héma-Québec collaborates on a constant basis with the SCS, and 2020-2021 was no exception with collaboration on studies to identify initiatives taken by blood banks throughout the world (see page 11) and to evaluate a non-destructive sampling method for blood products (see page 22).
- **The Leukemia & Lymphoma Society of Canada (LLSC):** SLLC's mission is to improve the quality of life of patients with leukemia, lymphoma and myeloma by funding research, supporting patients and advocating for their interests. Héma-Québec is associated with the SLLC in providing training and educational material for laboratory technicians and nurses working in the transfusion medicine field (see page 28).
- **TriPhyll:** TriPhyll is an industry leader in antimicrobial coatings. In the past year, Héma-Québec had an opportunity to collaborate on a project that aimed to evaluate the activity of an antimicrobial coating applied to the surface of storage bags for blood products (see page 16).
- **Université de Montréal (UdeM):** The UdeM is one of the leading academic institutions in Canada and the world, known especially for its research activities. Héma-Québec was privileged to be able to count on the many collaborators affiliated with this institution to evaluate an approach to detect antibodies to SARS-CoV-2 using surface plasmon resonance (see page 11).
- **Université Laval:** The Centre d'optique, photonique et laser (COPL) has made Université Laval an undisputed centre of research into nanotechnologies and optics. The scientists affiliated with the COPL were invaluable partners in evaluating an approach to detect antibodies to SARS-CoV-2 using surface plasmon resonance (see page 11).
- **Western University:** This university located in London, Ontario boasts several affiliated collaborators with cutting-edge expertise in immunology, which proved to be a determining factor in a study to clarify the role of various classes of antibodies in the immune response to SARS-CoV-2 (see page 11).

EXTERNAL FOUNDING

Research grants have been awarded to certain research projects to which Héma-Québec collaborated.

$355,000

Grant from the ministère de la Santé et des Services sociaux (MSSS) to conduct a study on the seroprevalence (in Québec) of SARS-CoV-2 antibodies, valid from April 1, 2020.

$30,000

Mitacs Accelerate research grant awarded to Steve Charrette (Université Laval) (lead investigator) and Danny Brouard (co-investigator), valid from May 20, 2020 to May 20, 2021..

$30,000

Mitacs Accelerate research grant awarded to Josée Laganière (lead investigator) and Yannick Doyon (CHU de Québec Research Centre, Université Laval, co-investigator), valid from December 1, 2020 to December 1, 2021.

$74,000

Grant from the Groupe de travail sur l'immunité face à la COVID-19 (GTIC) to conduct a study on the seroprevalence (in Québec) of SARS-CoV-2 antibodies, valid from April 1, 2020.

$30,000

Mitacs Accelerate research grant awarded to Steve Charrette (Université Laval) (lead investigator) and Lionel Loubaki (co-investigator), valid from September 1, 2020 to April 30, 2021.

$55,000

Mitacs Accelerate research grant awarded to Renée Bazin (lead investigator), Antoine Lewin (co-investigator), Andrés Finzi (CHUM Research Centre, lead investigator), valid from November 1, 2020 to October 1, 2022.

$31,000

Grant from Grifols awarded to promote and provide access to continuing education material in immunohematology, valid from December 1, 2020.

ORGANIZATIONAL STRUCTURE

Scientific activity revolves around two vice-presidencies, nine divisions and one administrative unit.

Vice-présidence aux affaires médicales et innovation
Dr. Marc Germain

- Direction médicale, microbiologie et épidémiologie — Dr. Christian Renaud
- Direction scientifique — Renée Bazin
- Direction des services infirmiers — Isabelle Rabusseau
- Direction de l'exploitation des tissus humains — Étienne Fissette
- Direction des opérations de recherche
- Unité d'épidémiologie, vigie et gestion des risques biologiques — Antoine Lewin

Vice-présidence à la médecine transfusionnelle
Dr. Nancy Robitaille

- Direction médicale hématologie et cellules souches — Dr. Catherine Latour
- Direction des cellules souches — Diane Fournier
- Direction des laboratoires de référence — Marie-Claire Chevrier
- Direction au partenariat clinique avec les centres hospitalier — Marie-Hélène Robert

Vice-présidence aux affaires médicales et innovation
Dr. Marc Germain

Provides medical, scientific and nursing expertise, as well as monitoring activities to offer services and safe biological products of human origin, integrating the most recent technological advances while ensuring the development and production of human tissues.

- Direction médicale — microbiologie et épidémiologie (Dr. Christian Renaud)
  - > Follows up presumed cases of transfusion-transmitted infections
- Direction scientifique (Renée Bazin)
  - > Supervises and supports all the scientific activities within the vice-présidence aux affaires médicales et innovation
- Direction des services infirmiers (Isabelle Rabusseau)
  - > Ensures that the collection of blood components is done under optimal conditions for the well-being of donors, using the most recent standards and knowledge applicable to all the techniques used
  - > Is responsible for inquiries regarding adverse reactions occurring during blood collection
  - > Answers questions from donors, including about blood donations and the types of collections
- Direction de l'exploitation des tissus humains (Étienne Fissette)
  - > Is responsible for harvesting, processing, qualifying, storing and distributing human tissues
  - > Collaborates with the Direction des opérations de recherche in developing new products and procedures for processing human tissues
- Direction des opérations de recherche
  - > Conducts research projects and the development of new products in the organization's five areas of activity
  - > Develop products and optimizes product qualification tests
  - > Supports scientific and technical activities related to Héma-Québec's five sectors of activity
  - > Evaluates technologies as part of call for tenders' processes
  - > Provides scientific support on technical or operational problems
  - > Works to optimize procedures and logistics in support of continuous improvement of operations
- Unité d'épidémiologie, vigie et gestion des risques biologiques (Antoine Lewin)
  - > Conducts epidemiological research projects
  - > Is responsible for the strategic monitoring of Héma-Québec's sectors of activity
  - > Provides expertise in risk management related to the biological products prepared by Héma-Québec
  - > Provides scientific, biostatics and methodology support to the design, management, drafting, analysis and publication of scientific articles and research protocols

Vice-présidence à la médecine transfusionnelle
Dr. Nancy Robitaille

Provides tests, services and specialized transfusion medicine and stem cell transplant products to help hospitals and our international partners provide the care needed by their patients as soon as possible, and participates in the production of educational materials related to transfusion medicine (e.g., Transfusion Camp in Toronto).

- Direction médicale hématologie et cellules souches (Dr. Catherine Latour)
  - > Supervises transfusion medicine Fellows and hematology residents
  - > Provides medical expertise in hematology and cell therapy
  - > Takes part in the donor selection criteria committee (including the joint committee with Canadian Blood Services)
  - > Participates in evaluating reported transfusion reactions and donors presenting with health problems not listed in the selection criteria
  - > Helps manage rare blood cases by providing expertise in immunohematology and platelet immunology
- Direction des cellules souches (Diane Fournier)
  - > Monitors the collection, preservation and maintenance of the stem cell bank
  - > Documents the genetic and molecular parameters influencing compatibility between stem cell donors and recipients in a registry accessible worldwide
- Direction des laboratoires de référence (Marie-Claire Chevrier)
  - > Conducts specialized immunohematology, platelet and HLA immunology tests for hospital blood banks
  - > Maintains an inventory of phenotyped packed red blood cells
  - > Performs HLA tests for the Stem Cell Donor Registry, the Public Cord Blood Bank and the registry of platelets with HLA compatible profiles
  - > Selects specialized blood products that are compatible with patients
  - > Is responsible for the rare blood program
- Direction au partenariat clinique avec les centres hospitaliers (Marie-Hélène Robert)
  - > Strengthens Héma-Québec's role as a partner
  - > Develops a personalized client-centred approach based on their needs
  - > Makes the hospitals' point of view known regarding all projects

HÉMA-QUÉBEC

www.hema-quebec.qc.ca