

Canadian Blood Services' Patient Engagement Forum

Fall 2023 meetings summary report

The Patient Engagement Forum is an ongoing initiative to help Canadian Blood Services engage patient organizations more frequently, more inclusively and in more robust ways. Such input helps CBS to better appreciate what stakeholders are hearing from patients, what issues and concerns are emerging, and what we could be doing differently to best meet patient needs.

The Forum meets twice annually in the spring and fall, with a collective joint session and individual community sessions for Blood, Plasma, and Stem Cells patient groups.

Introduction

Like previous meetings of the forum, the agendas and topics for discussion were determined through discussions and outreach to participant organizations. CBS held individual meetings with eighteen patient organizations in September and October, and as part of those conversations asked about topics of interest for discussion.

Forum meetings took place on:

- Plasma community: October 25
- Stem Cells community: November 15
- Blood community (rescheduled): November 28
- Joint session: November 23

What follows are brief summaries from each of those meetings and next steps. Action items can be found in Appendix A.

Meeting Summaries

Plasma community: October 25

The meeting's agenda included regular standing items such as a Formulary Program update and updates from Forum members, but the bulk of the session was focused on a discussion related to the drafting of a permanent National Immunoglobulin Shortages Management Plan.

National Immunoglobulin Shortages Management Plan

The NEBMC Secretariat came to the forum to ask Immunoglobulin (Ig) user groups about information, supports, and/or tools which would be helpful to patients in the event such a plan ever needed to be implemented, and how the full plan could be shared with, and reviewed by, patients and patient organizations.



Forum members provided detailed views, insights, and opinions on a combination of principles and tactics for communication guidance in the situation of a shortage:

Importance of providing details

Getting the information to the medical practitioners and patients as early as possible to alleviate stress, anxiety, concern, is absolutely vital. Transparency in the adjudication process is needed for perceptions of fairness. Details throughout the shortage will be needed, and paying attention to misinformation which may be circulating is important.

Importance of tone and sensitivity in communication

This is very delicate and complicated. It is going to be very scary if somebody gets that letter. There's may be a lot of anger if people think a shortage could have been avoided. Consider general communications as well as communication to impacted patients.

Importance of plain language

If the language is not clear, if the language is complicated, patients are not going to get it right from the beginning. It has to be very simple language that everyone and anyone can understand.

• Creating avenues for open communication

Communications have to be ongoing and not the responsibility of the patient organization, they will not be able to manage hundreds and hundreds of phone calls. There needs to be an established avenue to ask questions and get answers.

• Equipping clinicians

The people who are going to be having to explain a shortage are the practitioners who are treating people with respect to these issues, providing details and explaining the circumstances will be key and they will need to be properly equipped.

Specific tools

There could be ideas around tools that would be needed to notify a patient that they're not actually going to have an appointment one day, but I don't see how we could build that out? It would be nice to understand what hospitals/clinicians/MLTs thoughts are around managing that and how to communicate to patients.

Sharing news of the plans eventual publication

Appreciate the attention to avoid just putting this out there as information that this plan is happening, without some context, but if you just communicate well, that it is just a plan, you'll be OK. Patient organizations will circulate it and provide context that this is in place, but there is no shortage.



Members also provided input on the degree of engagement they have experienced to-date related to the project, and their desires for increased engagement throughout the remainder of the project. This feedback was heard by the NEBMC secretariat and the CBS Stakeholder Engagement team, and we committed to following up on these concerns.

Formulary Update with Dr. Sylvain Grenier:

PPRP product news on three products:

- The CBS recommendation to list HyQvia (an Ig product) has now been accepted by government and will be available to order in December. While it too quite a while, we are pleased that it was listed without restrictions. Customer letter here:
 - https://www.blood.ca/sites/default/files/2023-10/CL 2023-27.pdf
- We are expecting to get a decision on a recommendation to list an A1PI product in the near future. [Since the meeting date, a decision was provided - government accepted the CBS recommendation to list Glassia with restrictions]. Customer letter here:
 - https://www.blood.ca/sites/default/files/2023-11/CL_2023-31.pdf
- While our perspective on gene therapy for Hemophila B, is that it should be listed/covered by CBS, government has made a decision that this gene therapy will be handled alongside all other gene therapies, and therefore outside of CBS. It isn't clear, but this probably means that other gene therapies for conditions treated by PPRP may also be handled by a unified gene therapy strategy and therefore outside of CBS.

Comments on other innovative therapies:

- CBS is still in conversation with government about the criteria for inclusion on the CBS formulary. A decision about a particular gene therapy is not a precedent for decisions about any/all innovative therapies which may enter Canada in the future.
- Our process (since 2019) for considering a listing will continue to be in collaboration with CADTH and based on the evidence available.

Update on the Distribution Modernization Pilot in Alberta:

- Canadian Blood Services is engaging a specialty pharmacy network (Bayshore) to dispense and deliver (to patient's homes) plasma protein and related products (PPRP) that are used by patients at home.
- Scope: The project is being piloted with Hemlibra (emicizumab). Based on the available uptake information to date, Canadian Blood Services anticipates approximately 110 patients in Alberta in the first year. [Note: Since the meeting date, Alberta has decided to include Glassia in the pilot].

- The specialty pharmacy will provide clinical services necessary for dispensing, such as
 assessing the appropriateness of the prescription and ensuring that eligibility criteria are
 met. For the pilot, Canadian Blood Services will review eligibility centrally before product
 is dispensed at the pharmacy level.
- The project will be evaluated with several KPIs including improved patient access, improved hospital experience, improved adherence to listing criteria, and improved utilization monitoring.
- The pilot launched on October 30

Following Dr. Grenier's presentation, Forum members were invited to ask questions:

1. Does CBS anticipate concerns from unions about the distribution modernization pilot? Answer: No. Dr. Grenier explained that MLTs are in very short supply and Alberta blood bank advisors welcome this change and the expected reduction in their workloads.

Forum Member Updates / Comments / Questions / Issues:

To close the session, we held a participant roundtable.

- AnsweringTTP: We are in our own battle to access another innovative therapy, and CADTH has made a decision that is not favorable for us. We are concerned about seeing future innovative products, including monoclonal antibodies, listed on the CBS formulary and we need to know if we need a strategy to protect against the risk of bad decisions. This can be taken offline, but there are lots more innovations coming in the next few years.
- aHUS Canada: We are interested in helping to address the shortage of blood and
 plasma products. Could we get information about clinics to go to, we would like to post
 details on our Facebook or website to encourage donation? Ellis Westwood from
 Canadian Blood Services noted that the Stakeholder Engagement team will follow-up
 with patient organizations to walk them through setting up a Partners for Life (PFL)
 program, and detail other information resources available.

Stem Cells community: November 15

Stem Cells patient representatives joined Canadian Blood Services to talk about what is top of mind for patients. For the most part the hottest topic is CAR-T cell research and innovations in therapies for patients with blood cancers who need bone marrow transplant.

Stem Cell Program Highlights

Kathy Ganz, Director of the Canadian Blood Services Stem Cell Program shared an update from her team on recent activities and milestones of interest to Forum members:



Raising awareness of the need to grow and diversify the stem cell registry

The stem cell team was invited by MP, Taleeb Noormohamed to join him for a visit of the B.C. Women's Hospital and tour the Cord Blood program. The opportunity served to review how the Cord Blood program operates at the hospital, discuss opportunities for improvement and raise awareness for the program among Taleeb's constituency and prompt other MPs to do the same.

Hope on the Hill - Canadian Blood Services was pleased to be invited to co-host an event highlighting the need for parliamentary members and leaders to come together to champion people in their communities to join the stem cell registry. Hema-Quebec joined as well. The event resulted in 30 individual swabbings and many kits being taken away to share with others.

Celebrating 10 years since the Canadian cord blood bank opened

It's now 10 years since Canadian Blood Services began collecting cord blood in Canada. It has been wonderful working with families across 4 hospital sites to collect, process, and distribute cord blood units to support patient treatment. One highlight shared during the meeting was achieving a new milestone! In the first two quarters of our fiscal year, CBS distributed 8 cord blood units to international patients, a significant and proud moment for this important program. We also shared that Canada's cord blood bank overall is currently 66% ethnically diverse and we are working on increasing the diversity.

Canada Foundation for Innovation (CFI) grant for CAR-T for a CBS proof of concept

We were happy to announce that Canadian Blood Services received a Canada Foundation for Innovation (CFI) grant to develop a 'proof of concept' for CAR-T cell manufacturing. The project is now in progress, equipment is being ordered and a clean room is being installed, we will be happy to keep stem cell stakeholders up to date on progress in future meetings and as we achieve important milestones on this important innovation project.

Translating young donor study findings into action

CBS completed a study focused on how we can connect with and support youth engagement in donor recruitment. We are rolling what we heard into a project to bring tangible changes to how we connect with, engage and encourage youth to donate and keep donating.

Campaign in a box – turning a challenge into an opportunity

The COVID pandemic brought about some challenges for stem cell volunteer registrant recruitment with restrictions on public events. To solve this the team came up with a 'Campaign in a box' - this new kit offers a kitchen table discussion/recruitment kit for community champions and families. CBS is encouraging patient organizations to order one today and help to promote this easy-to-use toolkit through our patient portal. The stem cell patient portal can be found here: https://www.blood.ca/en/stem-cells/patient-resources-and-support.

Following Kathy Ganz's presentation, Forum members were invited to ask questions:

1. Are we collecting cord units in all hospitals?





Answer: No, Kathy explained that we collect units at 4 sites: B.C., Edmonton, Brampton, and Ottawa. These sites were chosen purposefully to target ethnically diverse donors.

- 2. What is the scope of the CAR-T cell 'proof of concept' grant project? Answer: Kathy replied that this is a project to develop a site to demonstrate our capacity to manufacture CAR-T cells in Canada within the health system. The scope is to establish and validate the lab, demonstrate its feasibility, and produce work instructions, etc. Our intent is to demonstrate that we could partner with medical institutions to support clinical trials. It is not ideal that all development in this area is largely based in the U.S. particularly when costs and complexities are considered.
- 3. What is on the patient portal? Answer: Kathy explained that the portal is a self-serve tool for patient groups, families, and individuals to access tools to host a stem cell drive, share their story or to share their messages. Action: Kathy Ganz offered to take the group through the portal next meeting.
- 4. On the topic of the 8 units distributed in Q1/Q2, do you know what those units supported? Is it cancer? Were these used for adults or children? Answer: Kathy responded that Canadian Blood Services does not receive granular details on how these units are used, however the request must be well defined and justifiable. It is usually a mix and adults and children. With children it is often in response to bone marrow failure. In adults it is most frequently for leukemia treatment. We also have access to and draw from the international registry for Canadian patient.

Innovations and Research in Stem Cells Transplantation – Dr. Matthew Seftel – Canadian **Blood Services**

Dr. Seftel gave a thorough presentation on the variability of finding a related and unrelated match for patients. Historically, a matched family donor has been the preferred option, but new research is challenging this notion.

He took us through a variety of fictional patient cases to show the variability of search factors associated with patients in need of a stem cell transplant. Factors like donor availability, suitability of siblings or parents, and how this is also dependent on their age, current health, and other genetic diseases of family members.

Dr. Seftel's presentation included a summary of the history of unrelated bone marrow transplantation in Canada. Just 30 years ago, there were only 300 volunteer donors in the registry, in 1992 there were 25,000, and today there are 440,000 – and we are committed to continuing to grow and expand the diversity of the registry! We set a goal of adding 20-25K more registrants this year.

We also heard about new and promising findings for voluntary unrelated, young, and mismatched cells. Dr. Seftel shared an exciting emerging technique involving the use of



cyclophosphamide as part of a new treatment protocol – this is an older drug that was refashioned by researchers at John's Hopkin's. It is inexpensive and is showing some very favourable results.

Questions following Dr. Seftel's presentation:

- 1. Under the new protocol you described what is the likelihood of graft vs host reduced?

 Answer: Dr. Seftel explained that graft vs. host is lower, it is still possible but not as common as other techniques. Infections may be higher, but these can be treated may require more recovery time.
- 2. How long are cells stored and how long are they viable? Answer: According to Dr. Seftel, cord blood is deep frozen and providing the equipment remains stable it can be stored indefinitely. Fresh cells collected from a donor to be transported to a patient for transplantation take 24 hours to reach their destination. The pandemic forced us to consider alternatives such as collecting and freezing fresh cells. More often now we are being asked to collect and freeze matched units in anticipation of the patient who is scheduled for transplantation as they prepare for the procedure.
- 3. Will we see people seeking to freeze their own (autologous) cells for the future?

 Answer: Yes, Dr. Seftel noted that there are commercial cell storage banks that already exist, and people are doing this now.

Forum Member Updates / Comments / Questions / Issues:

Myeloma Canada – Martine Elias:

Martine shared some information on multiple Myeloma. She also spoke to us about a business case prepared by her on CAR-T cell manufacturing in Canada which she shared with all participants before the meeting. Martine asked for help to raise awareness for the business case and to make connections with potential partners to move this work forward.

Martine shared that the business case offers a different way to approach bringing innovation in CAR-T cells forward in Canada. The case proposes taking bench research to trials, then to therapeutic practice in Canada, and once that is done to commercialize the therapies to fund ongoing research.

Dr. Seftel thanked Martine Elias for sharing the business case and acknowledged the hard work that went into preparing it. He also informed us that CBS is one element in the whole process of providing cellular therapies in Canada. He added that many academic and hospitals have large and well-funded projects in this area. Dr. Seftel commented that our intent is in making ourselves available to help develop products as they depart from the world of research and providing a uniform and high-quality product, and we will do that well if we are given the opportunity. Martine Elias offered to provide a letter of support when that is needed, as did Christina Sit.

- Martine and Christina shared that CAR-T treatment is top of mind for their patients who continue to ask: When can we get these treatments? When are the Phase 1 and 2 trials?
- Martine told us about a conference they held last year with researchers from Europe, and in particular, Spain researchers who have developed their own CAR-T for multiple myeloma.
- CBS agreed to help making connections for Martine to share her business case further. Christina Sit also confirmed support from Leukemia Lymphoma.

Leukemia Lymphoma – Christina Sit:

- Christina told us she's hearing from patients that they want peace of mind and therapies that work.
- She also shared that her organization has prepared submissions for HTA reviews and they are happy to do that if needed.
- She also shared that LLS works with clinicians that don't have pharma support for HTA consideration.
- Dr. Seftel told the group that while CBS plays a large role in certain products related to blood and plasma protein and hemophilia products but that where these cellular therapies go remains widely undecided.
- Christina offered to act as a bridge to bring patient voices to support innovation.

Blood community (rescheduled): November 28

The blood Forum explored three topics of particular interest to members representing patients who receive blood products:

- 1. An update on the ongoing risk-based decision making (RBDM) process on transfusion transmitted malaria:
- An introduction to the Canadian Transfusion Trials Group (CTTG) and opportunities for patients to engage with medical research; and
- 3. A briefing on donor eligibility changes recently made by Canadian Blood Services, as well as future planned changes.

Risk-Based Decision Making (RBDM) Process on Transfusion Transmitted Malaria

As part of 2022 Forum events, staff from Canadian Blood Services described a project underway to examine how the organization protects the blood system from malaria transmitted malaria. At the December meeting, staff returned to provide members with an update on the work, including what we heard from clinicians and patients during a recent engagement process.

To open the session, Dr. Eloise Tan, the Director of DEI at Canadian Blood Services, provided some important context for the RBDM, describing steps the organization is taking to reduce



Patient Engagement Forum Fall 2023 meetings summary January 2024

barriers to blood donation through community engagement and collaboration. She explained that Canadian Blood Services has been working with sickle cell patient groups, including the Sickle Cell Disease Association of Canada (SCDAC), and diverse Black communities to research, identify, and seek to address barriers to donation.

Dr. Tan added that, alongside these efforts, Canadian Blood Services is actioning DEI commitments to ensure that our donor base reflects Canadian society, especially in racial and ethnic diversity. She described an example, where Canadian Blood Services is convening a dialogue with digital influencers from Black and South Asian communities to explore how we can improve our donor recruitment and marketing on social media. Eloise emphasized that we are taking an engagement approach with communities, in the spirit of "not about us without us".

For Dr. Tan, it's important that Canadian Blood Services takes an evidence-based approach to how we engage and with which communities, based on population data and demographics from our own donor base, but an approach where we work in partnership with community. Eloise shared some examples of partnerships including with the Canadian Council of Muslim Women and with Autism Canada, where we are better understanding and removing barriers to donation. In these cases, we have been able to make the donation experience more comfortable through privacy screens, which also shows intersecting barriers faced by different communities.

Dr. Tan explained that the organization is not trading-off safety for inclusion at all. Rather, to bring three elements together: blood system safety, the right supply of blood to meet patient needs, and inclusivity.

With this important context about steps Canadian Blood Services is taking to make the blood system more inclusive, while maintaining system safety, Dr. Aditi Khandelwal presented on the specifics of the RBDM on transfusion transmitted malaria. Dr. Khandelwal is a Medical Officer at Canadian Blood Services, as well as a Hematologist and Transfusion Specialist at St Michael's Hospital and Sunnybrook Health Sciences in Toronto.

Dr. Khandelwal explained why malaria poses a risk to the blood system. As many know, malaria is an illness caused by parasites that are mainly transmitted by mosquito bites. In humans, the malaria parasites infect the liver and red blood cells and can hide unnoticed in the liver and occasionally enter the blood for decades, without causing any symptoms. She added that there are currently no suitable Health Canada-approved tests for donor malaria screening, so Canadian Blood Services has to rely on very broad screening questions about possible malaria screening exposures.

Dr. Khandelwal observed that malaria as a disease has affected human beings for thousands of years and yet there are still significant gaps in our understanding of malaria when it comes to transfusion medicine.

Aditi went on to describe the current malaria screening criteria, which are based on time spent in areas where malaria is endemic and where the US Centers for Disease Control and Prevention (CDC) recommends antimalarial prophylaxis:

- Short-term travel (24-horus to less than 6-months): 3 months deferral
- Longer-term travel or residence (6-months or more): 4-year deferral
- History of malaria (have had malaria): whole blood or platelets not collected, but individual are eligible to donate plasma and stem cells

She noted that the current malaria screening criteria were introduced in the 1990s after three cases of transfusion transmitted malaria before Canadian Blood Services was created in 1998. Since then, there has only been one recognized transmission of malaria from blood, which occurred in 2022.

Dr. Khandelwal described how Canadian Blood Services' malaria screening criteria have evolved over time to reflect new epidemiology and research findings (e.g., successful mosquito control measures on specific countries). Each of these changes required a submission to Health Canada, our regulator, to assess in in terms of maintaining the safety of the blood system. These changes are shown in the visual below, which Aditi included in her presentation.



To ensure the safety of the blood supply, each country makes region-specific decisions about risk mitigation strategies based on their local context. As a result, there is no uniform approach to malaria screening amongst blood operators around the world. In Canada, we identify appropriate risk mitigation specific to the needs of the patients across the country.

The effectiveness of any strategy is evaluated based on surveillance including (but not limited to) the monitoring, reporting, investigation, and analysis of events covering the entire blood system, from donation to transfusion to patients.





Dr. Khandelwal noted that Canadian Blood Services continuously reviews and updates its donor screening criteria as our understanding of disease patterns, blood testing and blood processing technologies advance. Our focus is on maximizing inclusion and ensuring the safety of donors and recipients.

She added that greater ethnic diversity in the blood system is critical to ensuring we can continue to maintain a reliable, accessible and sustainable system of life essentials to meet patient needs. She also shared that, at Canadian Blood Services, we recognize that donor deferrals for malaria disproportionately impact diverse Black and South Asian communities, and others who have lived in or traveled to malaria endemic regions.

Aditi added that we have come to fully understand, thanks to stakeholders and community members, the impact of current criteria for TTM. We have heard from stakeholders that criteria are exclusionary and have come to understand the stigma that blanket geographical or identitybased deferrals can perpetuate. That's why we are conducting the RBDM, to understand how the latest research and technology may permit introduction of a less restrictive eligibility criteria for people who have previously had malaria or have recently travelled from or moved from areas where malaria is endemic.

Dr. Khandelwal explained that the RBDM process follows an internationally developed methodology involving a thorough assessment of relevant safety, ethnical, economic, legal and contextual considerations, with a strong focus on stakeholder engagement. For the RBDM on transfusion-transmitted malaria, the engagement process included clinicians and members of patient organizations representing those who use blood products or have a long history engaging with Canadian Blood Services on the safety of the blood system:

Clinicians

- 1. Dr. Aisha Bruce, Medical Lead, Pediatric Comprehensive Sickle Cell Program of Northern Alberta, Medical Director, Pediatric Hematology, Division of Pediatric Hematology/Oncology/Palliative Care/Environment
- 2. Dr. Hanan Gerges, Transfusion Medicine Lead, Alberta Health Services, Hematopathologist, Assistant Clinical Professor, University of Alberta
- 3. Dr. Isaac Odame. Academic and physician specializing in sickle cell disease, Professor of Hematology and Oncology in the Pediatrics department of the University of Toronto, also holds the Alexandra Yeo Chair in Hematology at the University of Toronto.
- 4. Dr. Jacob Pendergrast, Transfusion Medicine, Pathology, Hematology, Interests: Hematopathology, Molecular and Cell Biology
- 5. Dr. Madeleine Verhovsek, Chief of Medicine, St. Joseph's specialist in sickle cell and thalassemia, hemoglobinopathy program at McMaster University.
- 6. Dr. Michael Hawkes, Program Director and Physician, Pediatric Infectious Disease, Associate Professor in the Faculty of Medicine, and Dentistry
- 7. Dr. Ziad Solh, Hematologist and transfusion medicine specialist at London Health Sciences Centre, Assistant Professor at Western University.

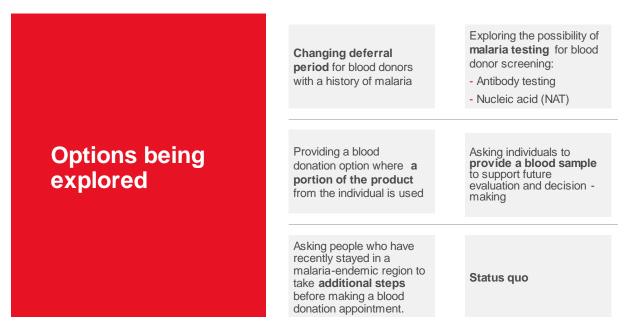
Patient Organizations

- 1. Cindy Anthony, Executive Director, Aplastic Anemia & Myelodysplasia Association (AAMAC)
- 2. Cynthia Musonda, Sickle Cell Network of Saskatchewan, member of Sickle Cell Disease Association of Canada (SCDAC)
- 3. David Page, Consultant Safety and Supply of Coagulation Products, Canadian Hemophilia Society (CHS)
- 4. Dr. Jean Walrond, PhD, President, Sickle Cell Foundation of Alberta, and Sickle Cell Disease Association of Canada (SCDAC)
- 5. Jennifer van Gennip, Executive Director, Network of Rare Blood Disorder Organizations (NRBDO)
- 6. Lanre Tunji-Ayaji, President and CEO, Sickle Cell Awareness Group of Ontario (SCAGO)
- 7. Riyad Elbard, (now former) President, Thalassemia Foundation of

Aditi explained that during interviews, participants were asked for their views on options for malaria screening being assessed, as well as on what Canadian Blood Services could do to



address the current impacts of malaria screening policies. She described the options being assessed under the RBDM (presentation slide):



Dr. Khandelwal provided a brief summary of findings from the engagement process. She said that participants recommended an approach that continues to balance risk, safety, and security of supply. Stakeholders also wish to see screening criteria which increases the donor pool and additional phenotype specific blood, as well as greater diversity of the donor base.

In addition, stakeholders want to see improvement in the Black blood donor experience in Canada, with specific efforts to build relationships with Black communities and the co-creation of community-specific information and education materials related to donation.

For the engagement process, Canadian Blood Services worked with Diversity Talk, an independent consultancy connected to sickle cell communities, to facilitate key informant interviews and develop a publicly available report on findings.

Aditi encouraged Forum members to read the <u>Diversity Talk report on what we heard from</u> stakeholders for more details.

In terms of next steps, Aditi commented that a final report outlining the results of the RBDM process will be shared with stakeholder participants and made publicly available in spring 2024. When the report is available, broader communication on the decision and implementation plans will be extended to stakeholder groups and the public once the path forward is defined.

Following Aditi's presentation, Forum members were invited to ask questions, make comments or share their thoughts.





- Sarah Ford of the Canadian Hemophilia Society asked: Can members receive a copy of the presented materials?
 - Answer: Ellis Westwood of Canadian Blood Services said, yes, copies would be distributed along with a summary report of the fall Forum meetings.
- Sarah also asked: How have sickle cell patient groups had been engaged in the RBDM work?
 - Answer: Dr. Khandelwal replied that almost half of the patients interviewed were representatives of sickle cell patient groups, including the Sickle Cell Disease Association of Canada and the Sickle Cell Awareness Group of Ontario. In addition, participants included leading experts who treat sickle cell patients, such as Dr. Isaac Odame and Dr. Jacob Pendergrast. Both patients and clinicians brought tremendous insights to the engagement and the broader RBDM study.
- Josie Sirna, representing the Thalassemia Foundation of Canada, asked: Is there data
 on the proportionality of asymptomatic malaria, and why do other blood operators have
 different malaria screening approaches?
 Answer: Dr. Khandelwal said that, unfortunately, there is no data on asymptomatic
 malaria carriership in Canada. From the little we do know, the proportion is low. But how
 low? We don't know.
- Josie also expressed concern that the risk of transfusion transmitted malaria may not
 outweighed by the risk of not meeting sickle cell patient needs for matched blood. Dr.
 Khandelwal replied that we have looked at this exact question and offered to present at
 the next Forum meeting to present what we have found. Ellis Westwood also suggested
 that we could follow-up with this information sooner, in writing.

Canadian Transfusion Trials Group: Community Engagement Working Group

Special guests, and Co-Chairs of the Canadian Transfusion Trials Group (CTTG) Community Engagement Working Group, Dr. Oksana Prokopchuk-Gauk (member, National Advisory Committee on Blood and Blood Products, and transfusion medicine physician and clinical hematologist with the Saskatchewan Health Authority) and Dr. Michelle Zeller (hematologist at McMaster University and Canadian Blood Services Medical Officer), , joined the Forum to provide members with more information about the engagement working group, and how they are seeking to engage patients in clinical research.

Dr. Prokopchuk-Gauk explained that the CTTG is a new initiative, created in February 2023, to promote collaboration and excellence in transfusion medicine. The CTTG is supported through a grant of \$2.5M over 5-years from Canadian Blood Services. CTTG's roots lay in the COVID-19 pandemic where a large group of researchers worked together across Canada through the CONCOR-1 trial to assess the effectiveness of convalescent plasma to treat patients with the virus. While the results of the trial were negative – it was not effective as a therapy – the



experience drew together Canadian transfusion medicine researchers, forming a network across the country. The CTTG emerged as an effort to maintain this collaborative approach and advanced the field of transfusion research.

She advised Forum members that the CTTG has a new website at https://canadiantransfusiontrialsgroup.ca/ and encouraged members to visit the site to learn more about the initiative.

Oksana outlined CTTG's goals:

Primary goal: to accelerate the conduct of pan Canadian high quality clinical trials to improve transfusion practice.

Secondary goals:

- 1. Develop innovative study designs, methodologies, and a shared data platform.
- 2. Foster mentorship and training of junior investigators.
- 3. Integrate basic translational studies into clinical trials design.

Dr. Prokopchuk-Gauk described the various working groups within CTTG, one of which is focused on community engagement, which is a venue for donor and patient input into CTTG projects and to incorporates donor and patient-important outcomes in network projects.

She thanked the Stakeholder Engagement team at Canadian Blood Services for being part of this CTTG working group.

Dr. Zeller continued the presentation by providing more information about the community engagement working group, explaining that its role is to provide advice to transfusion medicine researchers, as they begin their work, about the benefits of engaging patients and donors, and how to engage these stakeholders in their transfusion research projects.

The working group will develop resources to guide appropriate community engagement and help connect researchers with patients and donors willing to provide input and guidance to inform their research.

She explained that, currently, the working group is seeking one patient and one blood or plasma donor as members. Time commitment for members is around 6-hours per year to participate in meetings. Interested patients are encouraged to follow-up with Amie Malkin, the CTTG Coordinator at amie.malkin@sri.utoronto.ca.

Following the presentation, Forum members were invited to ask questions, make comments or share their thoughts.

 Josie Sirna of the Thalassemia Foundation of Canada, asked: Are the Co-Chairs were seeking to work with patient organizations or individual patients?



Answer: Dr. Zeller explained that the group would like to work with both, adding that patient organizations can help find individual members who are interested in being part of research projects, almost in a "rolodex" function.

 Josie also suggested that the working group include more than one patient member, perhaps to two or three; a suggestion that was welcomed by the Co-Chairs who agreed to bring that recommendation to the whole working group for approval.

Donor Screening Policy Changes

In the final agenda item, Dr. Mindy Goldman, Director of Donation Policy and Studies at Canadian Blood Services, provided an overview of recent changes to donor screening practices and others planned for the near future.

Reiterating comments made earlier in the meeting by Dr. Khandelwal, Dr. Goldman reminded Forum members that Canadian Blood Services is continually evolving donor screening criteria, based on new research, to protect the safety of the blood system. She recapped some of the major changes made in 2022-23:

- 1. Move to sexual risk behaviour screening for all donors
- 2. Addition of criteria for Mpox (formerly called Monkeypox)
- 3. Changes to deferrals for COVID-19 illness or exposure
- 4. Addition of deferral for long-acting pre-exposure prophylaxis for HIV (PrEP)
- 5. Removal of some deferrals for vCJD (aka 'mad cow' disease) in Saudi Arabia and most of Western Europe
- 6. Shortening of deferral period for cured cancers, melanoma to 1-year post-curative treatment

Dr. Goldman then provided a detailed briefing on post-implementation monitoring of sexual risk behaviour screening since its introduction in September 2022, representing a full year of data gathered by Canadian Blood Services. Sexual risk screening has replaced what was known as "MSM" criteria for gay, bisexual, and other men who have sex with men; criteria that evolved incrementally based on safety data and submissions to Health Canada to reduce the length of time-based deferrals.

As background, and as patient groups know, the original lifetime deferral for gay, bisexual, and other men who have sex with men (gbMSM) was implemented in the mid-1980s. Over time, with research findings and support from patient organizations, progressively shorter time-based deferrals were put in place, ending with a 3-month deferral in 2019. In September 2022, with new researching findings from our "MSM Research Program" and with support from stakeholders, Canadian Blood Services moved to a new way of screening where all donors are asked a set of questions to determine the risk of their sexual behaviours regardless of their sexual behaviours. Now, if the donor has had anal sex with a new partner, they will be deferred for 3 months from the date of last anal sex or from the date of their donation attempt. If the





donor has had more than one sexual partner, and anal sex with at least 1 partner, they will be deferred for 3 months from date of last anal sex or the date of their donation attempt.

Over the year since sexual behaviour-based screening was implemented, Dr. Goldman, stated that there has been <u>no change</u> in HIV rates in donations tested and <u>no</u> nucleic acid only (NAT) positive donations, which indicate recent infections. These correspond with the risk modelling submitted to Health Canada for the new screening approach where we outlined an expectation that it would not increase risk to the blood system.

Dr. Goldman then described our fall 2023 submission to Health Canada to remove remaining deferral criteria for vCJD. She briefly provided some history. vCJD is a novel prion disease first reported in the UK in 1996, caused by eating meat products from cattle infected with BSE (mad cow disease). The UK experienced a BSE epidemic, related to feeding practices in cattle. The high-risk period for vCJD acquisition from eating infected meat is from January 1980 to December 31, 1996. After measures were taken to control the risk, BSE levels fell to very low levels.

From a blood operator perspective, Dr. Goldman explained that donor screening criteria to reduce the risk of transfusion transmission of vCJD were introduced in the late 1990s as a precautionary measure and covered the at-risk period in the UK and other countries, such as France, Western Europe, and Saudi Arabia. Exposure in these countries was linked mainly to importation of UK beef, and in some cases, BSE in their own cattle. 4 cases of transfusion transmission of vCJD occurred, all in the UK.

Since that time, Mindy observed, vCJD cases have declined, with no new cases since 2016, and there have not been cases of transfusion transmission since 1999. As an additional safeguard since the 1990s, animal models suggested that removal of the white blood cells in blood components (leukoreduction) would reduce risk considerably, and universal leukoreduction has been in place in Canada for many years.

Due to the decline in vCJD cases and absence of transfusion transmission with leukoreduced components, countries are reassessing the need for the highly precautionary deferrals put in place in the 1990s. The FDA permitted US blood operators to remove deferrals for transfusion or residency, other than for the UK, France and Ireland, in 2020, based on risk modeling.

Dr. Goldman reported that risk modeling performed in Australia and Canada has concluded that risk of removing deferral criteria would be negligible, and because of this both Canadian Blood Services and Héma-Québec have put in submissions to Health Canada to remove remaining deferral criteria. Both were approved in late 2023.

She ended her presentation by adding that Canadian Blood Services is assessing the reduction deferral periods for some activities at elevated risk of HIV, HBV, and HCV infection to 3-months. These include prison time, a needle stick injury, graft, or illegal drugs with a needle. Both antibody and nucleic acid (NAT) testing is done for these viruses and window periods are less



than 21 days. The FDA has reduced the deferral period for most of these criteria to 3 months, and Canadian Blood Services is considering similar changes in Canada. As with all screening changes, Dr. Goldman emphasized that Canadian Blood Services prepares a submission to Health Canada, which makes a final decision as part of its role in regulating the blood system.

 Josie Sirna thanked Dr. Goldman for her presentation and explained that updated on screening changes from Canadian Blood Services medical staff are very helpful. She added that accessible and short, bite-size information on changes works best for the Thalassemia patient community and suggested the organization develop more of these. Ellis Westwood replied that Canadian Blood Services had recently develop a short, 2page plain language guide on the vCJD changes for patients and had shared this with patient organizations, including the Thalassemia Foundation of Canada. He thanked Josie for the feedback and added that his team would seek to develop more in the future.

Joint session: November 23

The joint session brought together all Forum members from plasma, blood and stem cell patient communities to explore topics of shared interest or importance.

Blood Collection and Inventory Challenges

As Forum members are aware from updates in our weekly stakeholder bulletins, Canadian Blood Services has spent most of the second half of 2023 in a Green Phase Advisory, with lower than planned inventory levels of fresh blood products. While we have consistently been able to meet patient needs for product during this time, it has raised concerns around potential shortages, and has required hospital transfusion medicine staff to work more closely with our supply chain personnel to closely monitor and manage inventories on the shelves in blood banks.

Kimberly Shaughnessy, Associate Director of Marketing at Canadian Blood Services, provided a detailed and transparent description of inventory challenges, the causal factors behind them, and what the organization is doing to respond. As part of our efforts, we are also asking patient organizations to help amplify and support our donor recruitment activities. Many Forum members have stepped up to do so in recent months and we are grateful for this help.

Kim began her presentation by noting that, as many Forum members understand, meeting patient needs for fresh blood products, which have short shelf lives, is about keeping supply and demand in balance. In practical terms, this means having the right number and composition of donors to produce the right number and type of blood units to meet the needs of patients. Too few donors risks shortages but too many donors presents a challenge because when donors donate less frequently (e.g. once every year or two), it becomes less of a habitual or repeatable behaviour.





She described a series of changes Canadian Blood Services' operating environment which have made it more difficult for the organization to recruit donors.

- Donor behaviour is changing: Canadian Blood Services, as well as blood authorities elsewhere in the world, are seeing important shifts in donor behaviour that are having significant impacts on their blood collection strategies. As a result of the COVID-19 pandemic, many workers are spending less time at downtown offices. Our past collection strategy located donor centres downtown, so make it easier for workers in nearby offices to donate during their workday. With the shift to remote work, we are rethinking ways for people to donate closer to home.
- Canada's population is growing rapidly and becoming more ethnically diverse:
 Driven largely by immigration this will increase the demand for blood products and intensify the need to encourage more diversity and inclusivity within our donor and registrant bases.
- Climate change: Kim explained that, in 2023, we have seen first hand the impacts of
 extreme weather events, wildfires and prolonged and more frequent power outages are
 just some of the factors that directly impact an organization's resilience and stability
 as a national blood operator we are very reliant on an integrated operational network
 spanning the country.
- Shifts with Technology: As organizations deploy increasingly powerful digital tools and analytics capabilities, consumers expect quick, convenient, and simplified interactions with organizations, along with personally tailored services. Need to consider more emphasis on robotics, machine learning and other forms of artificial intelligence (AI) to enhance safety and efficiency across the organization.
- Personalized medicine: The steady pace of scientific and technological advances is reshaping standards of care. As the use of genomics technologies in transfusion and transplantation continues to evolve, it will become possible to achieve unprecedented specificity, speed and throughput, leading to improved patient matching.
- Health systems are under pressure. The pandemic exacerbated capacity issues in
 hospitals across Canada, resulting in staff and resource shortages, as well as backlogs
 of patients awaiting surgery and other procedures. As these backlogs are addressed,
 there is a related increase in the demand for some products and services provided by
 Canadian Blood Services.

From a "demand" perspective, we saw a drop in hospital orders for red blood cells during the lockdown phase of the pandemic. This was the result of decreased trauma visit to hospitals as well as the cancellation of non-emergency surgeries. Post-pandemic, this demand has returned to pre-pandemic normal levels and this increase occurred in a very short period of time.





Furthermore, our donor base shrank during the pandemic and, post-pandemic, supply needs are being met with a smaller number of dedicated donors, which is unsustainable. In the short-term, we are activating our existing donor base to grow inventory but in the medium to long-term, our task is to grow and diversify the donor base. Kim shared that, starting in the fall of 2023, we have begun to see signs of progress in recruiting new donors. However, we still need to grow the size of the donor base by recruiting 100,000 new donors in the next year.

Kim ended her presentation by explaining that these collection challenges, together with changes in our operating environment caused by the pandemic, have led to Canadian Blood Services updating its corporate strategy. One of the main goals of the strategy is to build a more sustainable donor base for the future through three main ways:

- 1. Inspire donors and registrants to **give**, **aligning their profiles and preferences** with changing patient and health system needs.
- 2. Better define the characteristics of a resilient donor and registrant base and **increase the proportion of Canadians participating** in Canada's Lifeline.
- 3. Intensify efforts to **deliver an easy, flexible and personalized** donor and registrant **experience** in which everyone feels valued.

Following Kim's presentation, Forum members were invited to ask questions, make comments or share their thoughts.

Courtney Read from the Canadian Hemochromatosis Society commented that in her
patient community includes many who donate blood for therapeutic reasons but live in
rural areas or in larger centres like Kelowna without easy access to donor centres.
 Courtney said she was happy to hear that greater use of mobile donor centres for
locations like these is being considered.

Courtney also asked: *Is a way to let Partners For Life (PFL) groups know when there is a mobile donor clinic available in their local community?*Answer: Kim replied that, yes there is, however mobile clinics are usually fully booked well in advance. As a result, these notices are not often sent to local PFL groups because appointments are already booked.

• Tom Kerlow. from AHUS Canada, reported that his organization held a board meeting to discuss how they could help Canadian Blood Services' efforts to recruit donors. He said they are willing to put a link to donate on their website or on Facebook. Ellis Westwood from Canadian Blood Services thanked him for this offer and indicted he would follow-up with Forum members to explore ways to support donor recruitment that were manageable for their organization's capacity.





Josie Sirna, representing the Thalassemia Foundation of Canada, commented that she liked hearing about the neighbourhood campaign in Toronto, This City is in Our Blood, and asked: What the geographic radius around a donor centre is for recruitment efforts such as this?

Answer: Kim Shaughnessy replied that, for urban areas, it is as small as 1-2 km, although larger in a suburb or rural area. In the past, marketing has tended to treat these donors the same way, without fully recognizing the convenience level of the act of donating in each area. We are running pilot projects now to better understand these variables.

Josie noted that the Thalassemia Foundation of Canada is a member of the PFL Program at Canadian Blood Services, which they have found to be a very helpful "concierge" service for patient organizations looking to organize group donations. She offered the reflection that, which CBS staff are there to help, Partners do need to have a volunteer willing to coordinate donor sign-ups.

How Patient Organizations Can Help

As Kim Shaughnessy described, Canadian Blood Services is experiencing new, emerging challenges in recruiting donors. These are a result of individual and social changes caused by the pandemic. With this in-mind, support from our stakeholder communities, especially patient organizations, is important deeply appreciated. Several inspiring examples of patient organization support were presented during the meeting.

Jakob's Little Fighters

The first was from Paola Andrea Fernandez de Soto Abdul Rahim, board member of ImmUnity Canada, author, podcaster, and mother to "Jakob Little Fighter", a vibrant boy living with severe combined immunodeficiency (SCID). Jakob receives monthly IVIg treatments, derived from plasma donations. Right now, Andrea reported that Jakob is doing well but is waiting for gene therapy to become available as a final treatment option. Andrea described her donation campaign, called "Jakob's Little Fighters" for which she set a goal of 50 donations of blood or plasma during July and August 2023. Andrea setup the campaign through the Canadian Blood Services PFL program and spoke to the benefits and resources that the program offers. In addition, Andrea spoke to how she worked with local Canadian Blood Services staff to generate media coverage of her campaign, which helped recruit new donors and raise awareness of his condition and need for plasma. One of her takeaways from the experience was the power of a local story to motivate people to donate. Another was the benefit of working with a celebrity champion (Tanner Boser, UFC Fighter) and the power of social media to reach people. Andrea ended her presentation by reporting that Jakob's Little Fighters met its goal of 50 donations, culminating in a media event at the Edmonton Canadian Blood Services donor centre on Jakob's birthday. Images from the campaign are included as Appendix B. Canadian Blood Services sincerely thanks Andrea, Jakob, and the donors they helped us connect with.



Patient presence at plasma donor centre grand openings

The second inspiring example was from the GBS/CIDP Foundation of Canada, who have partnered with Canadian Blood Services to help with the opening of new plasma donor centres. Donna Hartlen, Executive Director of the Foundation explained that patients with GBS, CIDP or MMN are treated by immunoglobins as first-line therapies. Donna described the Foundation's approach as being one that brought donors and recipients together, to understand the story behind the need for donation. Canadian Blood Services had a booth at the Foundation's national conference earlier in 2023, which helped patients learn more about CBS. Canadian Blood Services followed-up to explore ways in which the Foundation could support the opening of new plasma donor centres across the country. The Foundation used its volunteer database to find local patients who can attend opening ceremonies, share their story with donors, and help raise awareness of the need for plasma donations to provide therapies patients need. The partnership with Canadian Blood Services has identified some important learnings. There needs to be close coordination between CBS staff and patient organization staff or volunteers. The Foundation has identified a single point-of-contact, their volunteer coordinator and patient advocate, for Canadian Blood Services to liaise with. That person can connect CBS with patient volunteers and then step away. Canadian Blood Services is responsible for all event details and providing the patient with all the information and resources they need, and Canadian Blood Services will reimburse their travel expenses for attending site opening events.

Donna ended by underscoring the value of Canadian Blood Services attending patient organization conferences and other events. She encouraged Forum members to let the organization know when they are taking place and to invite staff to participate. Donna then shared an idea for Canadian Blood Services to create a shared calendar so that patient groups can see what events others are organizing to avoid scheduling conflicts or competing for expert speakers, as well as to plan to attend each other's events. Ellis Westwood, the Canadian Blood Services staff member facilitating the meeting, expressed strong support for the idea and committed to creating one early in 2024.

Update on Draft Canadian Blood Services Strategic Plan

Earlier in 2023, Canadian Blood Services notified Forum members that the organization was revisiting its corporate strategic plan coming out of the COVID-19 pandemic and invited them to participate in an online engagement process to help shape the direction of that strategy.

Lise Simpson, Director and lead for our renewed corporate strategy, attended the joint session to provide an update on the development of the strategy: what we heard from patient organizations and other stakeholders about priorities for our new strategy, and early key components of the new strategy.

Lise began by explaining the decision to refresh our corporate strategy. She explained that during the pandemic, the organization was tracking important shifts in our operating environment, particularly in the area of changing donor behaviours. These change drivers have

Patient Engagement Forum Fall 2023 meetings summary January 2024

caused us to rethink and re-orient parts of our current strategy and to consider new strategic priorities.

Since we published our previous strategic plan, *Keeping the Promise* (in 2019), the environment in which Canadian Blood Services operates has changed significantly. Economic headwinds are creating an unpredictable environment, Canada's population is growing rapidly and becoming more ethnically diverse, technology transformation is only accelerating, health systems are under pressure, and personalized medicine is gaining momentum.

The online engagement we conducted provided us with important perspectives from patient and clinician communities. Lise commented that, together with our own research and analysis, what we heard from stakeholders played an important role in forming the strategy's emerging directions. She provided specific information on what we heard and how it has been addressed or incorporated.

Some of what we heard from stakeholders	How it has been reflected in the renewed Canadian Blood Services corporate strategy
Focus on safety and security of blood system and need for donors	 Continuing to focus on operational excellence and system resilience. Increasing collections through expansion of CBS plasma centres. Growing our donor base to the right size and composition to fulfill current and future needs.
Ensure equitable access to plasma protein and related products (PPRP) and monitoring, tracking and collection of utilization data for these products	 Continuing to effectively manage the national formulary of plasma protein and related products (PPRP). Using patient-level analytics to advise health systems on PPRP prescribing practices to help them meet patient needs and optimize product utilization.
Support increased engagement with racialized communities to better meet patient needs	 Recruiting more donors and registrants from diverse communities through an inclusive approach focused on relationship building. Addressing barriers and co-create strategies with underrepresented groups.
Focus on supply chain expertise and domestic access and control of products	Building a complete immunoglobulin supply chain in Canada through a strategic alliance with Grifols – additional plasma collection and domestic fractionation facility.



Patient Engagement Forum Fall 2023 meetings summary January 2024

Some of what we heard from stakeholders	How it has been reflected in the renewed Canadian Blood Services corporate strategy
Collect, manage, and use data in beneficial ways	 Improving stewardship of data collection and utilization. Employing data and analytics to gain insights into donor and registrant behaviours and preferences to create better experiences. Combining data and analytics with qualitative information to help drive problem-solving and decision-making.
Use CBS's unique position to capture population-level health data and assist in tracking emerging health trends/issues	 Partnering with public health to extend the impact of our testing and surveillance capabilities and infrastructure. Strengthening our surveillance, research and testing capabilities to investigate novel and emerging pathogens.

Overall, Lise spoke to key themes in the current working draft of the strategy. These are:

- Improving patient outcomes through better product matching and a secure, optimized product and service portfolio
- Leveraging our capabilities and infrastructure to advance the broader health system
- Growing a flexible, sustainable and multi-product focused donor base
- Developing our employees to be ready for the future
- Embedding resilience in our systems and investing in our digital and physical infrastructure



Patient Engagement Forum Fall 2023 meetings summary

January 2024

While the refreshed strategy still has to be approved by our board of directors, Lise described the four priority area in the refreshed strategy:

Summary of the four strategic priority areas

Products &



Match products and services to patient and health system needs

We will continue to offer a portfolio of products and services that anticipates changing clinical practice and patients' diverse needs — helping to improve health outcomes, ensuring sufficiency of Ig supply and leveraging our capabilities to contribute to Canada's health systems.

Donors & Registrants



Grow and diversify a flexible, sustainable donor and registrant base

As medical advances and social change continue to transform health care, it is more crucial than ever to have a resilient base of donors and registrants that can meet patients' needs.

People & Culture



Invest in our people culture

As we build the capabilities to realize our strategic ambition, our employee experience and culture must be designed to foster inclusion, development, flexibility and accountability.

Digital & Physical Infrastructure



Enhance our digital and physical infrastructure

Our strategy is enabled by an increasingly responsive and resilient infrastructure — an infrastructure that was tested during the pandemic and <u>is in need of</u> investment and modernization.

Next Steps

The next round of meetings will take place in the Spring of 2024. Invitations and calls for agenda items will be sent well in advance.

Thank you all for your participation!



Appendix A: Action Items

Action item	Follow-up / Status		
Blood Forum			
Canadian Blood Services to provide more information on how well the organization is meeting the needs of sickle cell patients under current malaria screening criteria	Canadian Blood Services is working on providing this information.		
Canadian Blood Services to share follow-up message from the CTTG Community Engagement Working Group Co-Chairs	Expected from the CTTG working group shortly.		
CTTG Community Engagement Working Group Co-Chairs to propose increasing the number of patient representatives on the group	Co-Chairs to raise at next Working Group meeting		
Plasma Forum			
4. 1. Ig Shortage plan project team will proceed with further planned engagement as described, as well as consider comments regarding additional engagement.	Completed – sent by email to Forum members		
5. 2. 1:1 meetings with forum members to walk through information about PFL program, and where to find details on clinics to go to, so patient organizations are equipped to encourage donation.	Canadian Blood Services to follow-up		
Stem Cells Forum			
6. HLA Redundancies: Share new publication link and discuss at next meeting	Canadian Blood Services to follow-up		
7. Share link to CBS stem cells patient portal	Completed – in summary notes.		
Joint Session			
8. Share copy of marketing presentation delivered by Kim Shaughnessy	Completed – sent by email to Forum members		
Share copy of CBS corporate plan presentation delivered by Lisa Simpson	Completed – sent by email to Forum members		
10. Schedule DEI follow-up for future meeting	CBS to discuss with DEI team		



Appendix B: Images from Jakob's Little Fighters Campaign















