Building a Platform for Meaningful Patient Partnership to Accelerate "Bench-to-Bedside" Translation of Promising New Therapies

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Abstract

Engaging patients as partners in the design and execution of early-phase clinical trials offers a unique opportunity to ensure patient perspectives are considered. Here we describe our experience partnering with four individuals with lived experience of blood cancer to co-develop documents and services to support participants of an early-phase trial. Through regular team meetings, patient partners co-developed a visual informed consent document and a non-technical summary of the informed consent document to facilitate participant understanding of trial procedures. Overall, patient partners highlighted important trial components that would not have been identified without their input.

Key Points

- Patient partners identified areas of a clinical trial that needed more attention and informed the development of patient-facing informed consent documents and a policy brief.
- Co-development of the project was facilitated through regular virtual meetings and a final face-to-face meeting.
- All team members described working together as a positive experience.

Patient Engagement Approach and Structure

Background and aim of patient engagement

Canadian-Led Immunotherapies in Cancer trial (CLIC-01) is an early-phase clinical trial assessing chimeric antigen receptor T (CAR-T) cell therapy. CAR-T cell therapy is a promising immunotherapy to treat hematologic malignancies where a patient's own T cells are genetically engineered to identify and kill cancer cells (Lee et al. 2012). CAR-T cell therapy has demonstrated efficacy as a novel treatment (Grigor et al. 2019; Jackson et al. 2016; Lee et al. 2015). In order to create a patient-centred trial, our team had previously collaborated with two patient partners on various projects to compile evidence for the co-development of the CLIC-01 trial protocol (NCT #03765177). This research program was titled "Getting Better Outcomes with Chimeric Antigen Receptor T-Cell Therapy" (GO-CART) and has been summarized elsewhere (Foster et al. 2020). When the GO-CART program came to a close, we wanted to extend engagement beyond protocol development to further improve trial processes and support clinical trial participants. To achieve this, we initiated a project funded by the Ontario Strategy for Patient-Oriented Research (SPOR) SUPPORT Unit (OSSU) Engaging Multi-stakeholders for Patient Oriented-research Wider Effects and Reach (EMPOWER) Award. We worked with patient partners to enhance patient-facing informed consent documents, plan a peer support panel and co-develop a policy brief.

P = Patient partner.

Recruitment of patient partners

Four patient partners were recruited to our research group. One patient partner continued their involvement from the GO-CART program into the OSSU EMPOWER Award initiative and, as a result, had a detailed understanding of the CLIC-01 trial. Another patient partner reached out to our research group after hearing about the GO-CART program at a BioCanRx Summit for Cancer Immunotherapy conference and expressed interest in joining our team (BioCanRx is a federal government–funded Network of Centers of Excellence that supports partnerships among industries, academic institutions and patient organizations) (https://biocanrx.com/). She brought a completely novel perspective as she had participated in a similar trial in the US when the immunotherapy was under investigation there. Two additional patient partners were identified and recruited through the circulation of an advertisement by the Leukemia and Lymphoma Society of Canada (https://www.llscanada.org/).

The onboarding process and team structure

All patient partners were formally onboarded to the research team. This process included a meeting (in-person or virtual) with research assistants, where we provided details of the previous GO-CART project, an overview of the CLIC-01 trial and how the OSSU EMPOWER project would support previous work. Team members' headshots and biographies were presented to provide patient partners with information on team members' interests and expertise. We also allocated a portion of the meeting to discuss patient partners' expectations, availability and what they hoped to gain from the experience. To ensure that engagement was supported throughout the research project, we co-developed a Terms of Reference document outlining the agreed-upon roles and responsibilities of each team member (Alberta SPOR SUPPORT Unit 2018).

Planned engagement

From inception, the aim of patient engagement was to obtain the patients' perspectives on how to improve the experience for CLIC-01 trial participants. Though potential areas for collaboration were identified in advance (e.g., informed consent documents, peer support panel, policy brief), specific details were left open for discussion as we wanted patient partners to play a role in the planning process. We scheduled bimonthly team meetings, where we worked together to (1) identify areas and elements of the CLIC-01 trial that required support and (2) co-develop services and documents to meet patient needs. Additionally, we aimed to develop a policy brief on patient engagement in early-phase clinical trials to support researchers and institutions.

Meetings and engagement activities

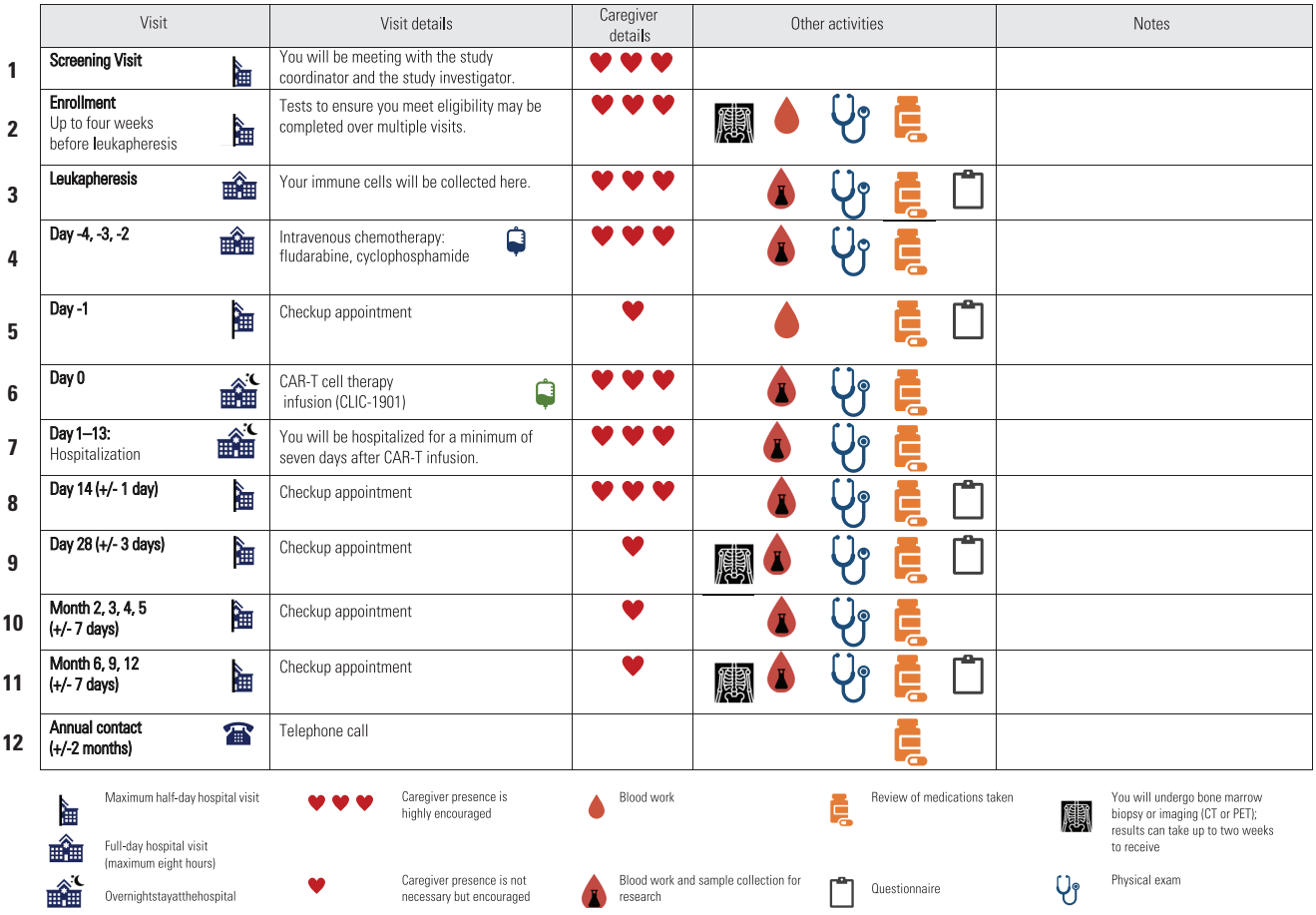
To finalize project deliverables, we organized a full-day face-to-face meeting (November 2019), where all team members could meet in person as well as virtually to discuss the project's progress and the next steps.

Our first engagement activity focused on supporting the informed consent process. Because CLIC-01 is an early-phase clinical trial, the informed consent documents can be lengthy and technical (Brehaut et al. 2012, 2015; Somers et al. 2017). Furthermore, potential trial participants are unlikely to have other available treatment options. These two trial characteristics further highlighted the informed consent process as an important trial component wherein participants may need additional support in understanding what participation in the CLIC-01 trial entails. Patient partners suggested that more user-friendly documents could help support participants' understanding of the trial and allow them to easily share information about the trial with friends and family. To address this, we co-developed a visual informed consent document and a one-page non-technical summary. As a group, we went through the informed consent document to identify sections that could be simplified and presented graphically. The schedule of assessments was highlighted as an important component because it outlines involvement (i.e., hospital visits, procedures). We formatted the schedule of assessments as a one-page graphical timeline where procedures were represented by colourful icons (Figure 1).

One patient partner highlighted the supportive role played by caregivers because they are usually present for procedures and hospital visits. In order to address this issue, we added an icon to denote the length of hospital visits, which would allow caregivers to anticipate visit length and provide them with the opportunity to make scheduling arrangements if necessary. At the close of the project, visual informed consent documents were finalized and sent for review by the Research Ethics Board (REB).

We also co-developed a policy brief outlining ways that funding agencies can encourage uptake of patient engagement in the development and conduct of early-phase clinical trials. We co-designed three approaches that funding agencies can adopt to encourage researchers to engage patient partners in the development and conduct of early-phase clinical trials, including (1) making web-based educational resources on patient engagement available, (2) implementing a checkbox on grant applications to indicate the intent to engage patients and requesting a written report from successful applicants as an interim analysis and (3) incorporating patient engagement within the funding agency. Further details will be outlined in our policy brief (registered on Open Science Framework: https://osf.io/6jequ/).

FIGURE 1.
Visual informed consent document



A third engagement activity was to organize a peer support panel consisting of individuals with lived experience of hematologic malignancies or having experience participating in a clinical trial. In fact, one patient partner had previous experience as a peer support mentor, and their perspective informed the overall direction of the peer support plan. For example, an online platform was identified as the preferred format over mentor–mentee conference calls to avoid emotionally burdening mentors.

Unfortunately, we encountered several hurdles to developing an online peer support panel, including preserving anonymity and ensuring that the platform would be accessible outside of the hospital setting while maintaining confidentiality. As a result, we decided that partnering with a patient organization that has an established peer support infrastructure might help us overcome these hurdles. We plan to continue exploring this approach in future work. Further details of engagement can be found in Appendix 1: Table A1, available online at www.longwoods.com/content/26770.

Assessment of engagement

In order to improve patient-partner engagement in future initiatives, we assessed engagement methods at the face-to-face meeting by disseminating a survey to patient partners. The final evaluation consisted of nine questions (a combination of surveys developed by Patients Canada [Maybee et al. 2016] and the Patient and Family Advisory Council at The Ottawa Hospital [https://www.ottawahospital.on.ca/en/clinical-services/deptpgrmcs/programs/cancer-program/patient-and-family-advisory-council/]). Through the questionnaire, our patient partners expressed some issues with the combined virtual and in-person attendance to our last meeting. We recruited two additional patient partners after the project started, but the research team did not have the funding to provide travel reimbursement for the additional patient partners to attend the face-to-face meeting. This caused an unintended divide between local and non-local patient partners; non-local patient partners expressed feeling disconnected from the rest of the team at the face-to-face meeting.

> Although challenging, all recruitment should take place as early as possible in the program. It would have been more effective if all four patient partners were able to attend the full day face-to-face meeting. It was challenging for those who had to attend by teleconference. (Terry Hawrysh)

Obstacles

Despite the successes of our project, we encountered several obstacles to engagement that should be noted. First, it was challenging to identify patient partners within the timeline of the program. Two patient partners were involved from the onset of the study; however, it was difficult to identify and onboard additional patient partners. With that said, partnering with an established organization (e.g., The Leukemia & Lymphoma Society of Canada in our case [https://www.bloodcancers.ca/]) to circulate an advertisement was an effective strategy for patient-partner recruitment.

Second, patient partners expressed disappointment with the delay in the implementation of the informed consent resources. Due to the COVID-19 pandemic, the REB shifted focus to approving COVID-related research materials and projects. As a result, it took several months to gain approval to include the documents as a part of the informed consent process.

> [It was disappointing] seeing that the initiatives that we tried to start didn't come to fruition because of various hurdles. This prevented [us from] seeing a direct impact of our involvement in the program. (Stefany Dupont)

In retrospect, this disappointment could have been mitigated by providing regular updates (e.g., monthly) on the project's progress and including the visual informed consent form with the initial clinical trial submission to the REB to maximize the use of these documents. The documents have now been approved for use and will be implemented for future patients recruited to the clinical trial.

Equity, diversity and inclusion

Given the obstacles faced when identifying and recruiting patient partners to the research team, equity, diversity and inclusion were not at the forefront. With that said, it is clear that inclusivity of diverse perspectives is of the utmost importance in patient engagement and cancer research (i.e., cancer does not discriminate). From our experience with recruitment and our improved understanding of organizational roles in identifying interested patient partners, we may be able to prioritize these issues in future engagement efforts.

Compensation and acknowledgement

All travel expenses (transportation, accommodations, parking, meals, etc.) were reimbursed for patient partners who attended the face-to-face meeting in person (according to institutional policies at The Ottawa Hospital). Two local patient partners were offered compensation for attending the full day face-to-face meeting in person. The method of compensation and amount were informed by the SPOR Evidence Alliance Patient Partner Appreciation Policy and Protocol (SPOR Networks in Chronic Diseases and the PICHI Network 2018). All patient partners were acknowledged as co-authors on manuscripts.

Next Steps

The OSSU EMPOWER Award project inspired the development of a new program, Making Patient Partnerships A Reality in Very Early Phase Clinical TriaLs (MARVEL) funded by BioCanRx (https://biocanrx.com/csei7-lalu). The MARVEL program will aim to develop a patient engagement platform to facilitate engagement throughout the development and conduct of four unique early-phase research initiatives (including the ongoing CLIC-01 trial).

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Our Experience with Patient Engagement

Overall, our experience was positive. Patient partners identified patient needs that we could not have identified without their perspectives (e.g., importance of emotional support). Patient partners stated that their involvement in the OSSU EMPOWER project was positive, gratifying and educational. They noted that they believed their contributions were valued and had great influence on the course of the project and the final products.

> As a patient living with blood cancer, I was especially encouraged with the work done on simplifying the informed consent process through the creation of lay summaries and a visual rendition of what to expect during the trial. Undergoing a clinical trial can be an overwhelming experience for patients and their families; the support methods developed by the team will go a long way to help them. This should greatly benefit potential trial participants in their understanding and evaluation of the research approach, time commitment, costs and risks associated with trial participation. (Terry Hawrysh)

> It was an opportunity for me to "give back" and ensure that people facing the same situation I faced in 2017 [cancer diagnosis] had a smooth experience. (Stefany Dupont)

We have compiled the following lessons learned that would help guide future initiatives:

- Patient engagement activities were identified organically. At the onset of the project, specific details were left open for team discussion, which generated most of the project deliverables.
- It is important to have an open discussion about patient partners' availability, interest and acknowledgement (compensation, reimbursement, co-authorship, etc.) while providing sufficient background on the project.
- Terms of reference documents are helpful in setting expectations.
- Virtual peer support panels require extensive legal, technological and administrative support, which were prohibitive in our project.
- Maintaining an open line of communication is important (e.g., circulating regular project updates, and communicating how patient-partner feedback was implemented).

Key Messages and Implications

Early-phase clinical trials offer a unique opportunity for patient partners to provide input early in the "translational" pipeline of therapy development. Engagement at this phase of research is particularly impactful because it allows for the streamlining of researchers' priorities and those of the ultimate end-users of the technology. Incorporating the patient's perspective may help improve chances of a successful trial (reducing obstacles, providing necessary supports, clear and understandable information, etc.) and overall translation of the therapy to practice, which is essential for early-phase clinical trials (Crocker et al. 2018; Gasson et al. 2015). Here, patient partners were able to identify areas of the clinical trial that needed more attention. This would not have been accomplished without their input. HQ

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Stefany Dupont, BSOcSC (Hons), is an aspiring school teacher. Stefany is currently in remission from acute lymphoblastic leukemia and lives in Montreal, QC.

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