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### Cover Page Footnote

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# Meaningful engagement of patients and families in a complex trial of advance care planning in primary care

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## Abstract

Engagement of Patient and Family Advisors (PFAs) is increasingly recommended as best practice in research. During the design and conduct of a large trial of advance care planning (ACP) in primary care, we expanded on the funder's (Patient-Centered Outcomes Research Institute®) requirement for an engagement plan and sought to develop an innovative approach to fostering and sustaining meaningful engagement of PFAs throughout all phases of the trial. Structures were developed that integrated PFAs into planning and provided the foundation for their ongoing participation. A continuous quality improvement approach became the framework for ongoing engagement. This involved setting goals; collecting data through surveys, interviews, and observations; and using data to inform revisions to the engagement approach. We also tracked PFA activities and ideas and documented how they impacted the trial. This article summarizes our experience and describes the challenges we faced and how we addressed them. We also outline key lessons learned about encouraging participation; approaches to preparation and coaching; fostering equity across PFAs and other roles in the trial team; creating a range of opportunities that match PFA skills, preferences, and expectations; the importance of regular feedback; and the need for training of all trial staff. Our experience demonstrates that successful and impactful engagement is possible but requires consistent commitment and intentional dedication of sufficient resources.

## Keywords

Patient experience, patient-centered care, patient and family engagement, patient- and family-centered care, measurement, quality of life, quality of care, healthcare, communication, partnership, patient family advisor, advance care planning, end-of-life, serious illness, care partner

## Introduction

Patients with chronic conditions often experience functional and cognitive decline over an extended period of months or years.<sup>1,2</sup> As illnesses become serious in the last months and years of life, care can be invasive and harmful if the default is “all possible” medical options. Instead, there should be explicit consideration of patient and family preferences. Advance care planning (ACP) is a process that allows patients, families, and clinicians to discuss what matters most to patients, identify goals, and establish a foundation for decisions about future healthcare that supports patient values.<sup>3,4</sup>

ACP involves assessing patient and family understanding of health status and possible trajectories and then eliciting values, preferences, and goals related to future medical tests and treatments.<sup>4</sup> These conversations can be difficult and challenging for all involved.<sup>5,6</sup> They can be made easier by providing a clear structure and patient-tested language that clinicians can use to initiate and engage patients and

families in conversations as well as guidance for healthcare settings about options for identifying appropriate patients and integrating serious illness conversations into workflows.<sup>7,8</sup>

The Meta-LARC ACP Trial (The Trial) was designed to compare team-based to individual clinician-focused approaches to ACP in primary care for patients with serious illnesses. The hypothesis was that a team approach might be more effective in busy, under-resourced primary care practices. We used an existing ACP program, the Ariadne Labs' Serious Illness Care Program (SICP), which had been developed and tested for individual clinicians, mostly in oncology, and adapted it for primary care and created a team version. Seven Practice Based Research Networks (PBRNs), five in the U.S. and two in Canada, each recruited six primary care practices to The Trial, for a total of 42 practices. This was a cluster randomized trial, meaning that practices (the clusters of patients) were assigned by chance to one of the two ACP approaches and were provided training and support according to their

assigned approach. Patients were referred to PBRN staff for enrollment and data collection after their initial serious illness conversation, with follow-up surveys 6 months and 12 months later. The protocol for The Trial was published<sup>9</sup> and The Trial is registered with ClinicalTrials.gov (NCT03577002). An overview with more information about the study is provided in Appendix A.

The Trial was funded by the Patient-Centered Outcomes Research Institute® (PCORI®) (Award PLC-1609-36277). PCORI® required the development of an engagement plan to complement the research protocol, reflecting the commitment of PCORI® to supporting research that addresses questions and outcomes meaningful to patients and caregivers.<sup>10,11</sup> Because serious illness conversations must be patient-centered to be effective, incorporating the lived experiences of patients and families was essential to the success of our study. The purpose of the engagement plan was to operationalize this commitment and guide collaboration with patients and families in the design and conduct of The Trial. Our ultimate engagement goals were to ensure that engagement with Patient and Family Advisors (PFAs) was meaningful; that PFAs were able to make substantive contributions to a successful trial; and that trial results would inform future decisions made by patients, families, clinicians and healthcare administrators about ACP.

In this article, we describe how we expanded the PCORI® required engagement plan to create an improvement-focused approach to meaningful engagement of PFAs in the development and conduct of a large trial. We describe our initial efforts, the challenges we encountered maintaining engagement across the different phases of a complex trial, adaptations of our strategies to these phases, the impact engagement had on the trial, the pragmatic lessons we learned about supporting engagement, and how we intend to apply this experience to future research.

### PFA Involvement Throughout the Trial

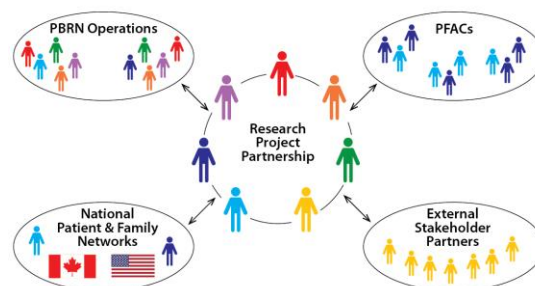
From its inception in 2016 to the completion of data collection and primary analyses in 2022, The Trial

employed a systematic approach to involving and collaborating with patients and families with lived experience of ACP. As a result, and described in the following section, PFAs impacted **every aspect** of this trial.

Starting in April 2016, early conversations with patients about how primary care practitioners could have frank, in-depth conversations about end-of-life planning and care in the context of serious illnesses established the foundation for PFA input that influenced the research proposal. In the project budget, engagement-related costs accounted for 6% of total costs and supported a designated Coordinating Center, Engagement Manager, engagement consultants, and project staff at local PBRNs assigned to engagement support roles. The budget also supported ongoing technical assistance and consultation focused on skill development for the Principal and Co-Investigators, Engagement Manager, and other study staff in how to effectively engage PFAs and maintain their meaningful participation throughout The Trial. The goal was to integrate engagement into their research roles, impacting the current trial and sustaining robust engagement processes in future research. The Engagement Manager oversaw all processes that elicited PFA feedback and evaluated how to increase their meaningful contribution and impact on the research. PBRN staff, who were assigned an engagement role, worked directly with PFAs to integrate them into local PBRN research activities. Additionally, the budget also provided payment for PFA participation in ongoing activities as one of several ways to communicate the value of their contributions.

With the initiation of the PCORI award in 2017, the Coordinating Center developed PFA recruitment materials that defined characteristics of effective advisors and recruitment strategies for PBRN use (See Table 1), provided guidance for PFA selection as needed, and planned for ongoing PFA training and support. The seven PBRNs each recruited a local PFA and the Coordinating Center recruited two at-large PFAs (not affiliated with a PBRN) to serve on a project steering committee called the Research Project Partnership (RPP). The composition of The Trial’s RPP, engagement structure, and partnerships are illustrated in Figure 1.

**Figure 1. Patient, Family and Advisor Engagement Structure and Partnerships**



Actual PFA participation started with The Trial’s launch in November 2017 in Montreal, with an in-person PFA orientation conducted to prepare PFAs for their roles, build relationships among PFAs and with the Research Team (Principal Investigators (PIs), Engagement Manager, Patient Family Engagement Consultants), and answer questions about the study. PFAs then joined researchers and PBRN leaders for a 4-hour project launch meeting. Subsequently, in January 2018, surveys and interviews were conducted with PFAs to identify strengths and ongoing needs. Based on responses, the Coordinating Center provided additional information and clarification about the phases of the research study, a list of acronyms, and definitions on all materials. PFAs who were new to the research process were matched with experienced PFA “learning buddies” for support and mentorship(See Table 1).

Throughout The Trial, PFAs continued as members of the RPP. In the first year of the study (2018), monthly newsletters and virtual drop-in office hours were initiated to provide updates and access for PFAs to the PI and research staff. Responding to a request from PFAs. Also in the first year , quarterly PFA-focused meetings were initiated to better prepare PFAs for RPP discussions and provide dedicated space for their input. These meetings gave PFAs, engagement staff, and the PI an opportunity to more thoroughly discuss emerging issues, identify PFA perspectives and refine RPP agendas. In Table 2, we illustrate how these ongoing meetings influenced and impacted the study.

PBRNs served as the hub of the study, providing the primary relationship with both PFAs and participating clinics. Therefore, supporting PBRNs as they worked with

PFAs and clinics was an important component of the engagement strategy. PBRNs were surveyed about their experience with PFAs and coaching/training was provided as needed. PBRNs were encouraged to support clinics in engaging existing Patient Family Advisory Councils (PFACs) in supporting the study. The Coordinating Center developed and shared information about the study for use by PBRNs and clinic PFACs. A typical role for a clinic PFAC was to review initial and ongoing updates on the study and share questions, concerns or suggestions with the PBRNs and RPP as appropriate.

The engagement plan specified that PFAs would provide insight and input at each stage of the research study. To support PFA participation, throughout The Trial, the Coordinating Center outlined opportunities for input, responded to questions, and matched specific PFA interests to specific tasks. PFA contributions, initiated at the kick-off meeting in November 2017, continued through topic-specific workgroup participation, quarterly PFA meetings, quarterly RPP meetings, monthly PBRN operations group team meetings, and work with clinic PFACs. PFAs were involved in all aspects of the study and demonstrated leadership in key areas of training and dissemination (See Table 3).

**Monitoring PFA Impact: An Improvement Approach to Engagement**

To ensure that engagement was meaningful and authentic, an ongoing assessment was designed to ensure the successful integration of the voice of PFAs in all aspects of the research study. We developed an iterative approach to engagement activities based on a continuous quality improvement model. The Trial utilized a variety of

**Table 1. Recruitment and Selection of Patient and Family Advisors**

<b>Characteristics of Effective Patient and Family Advisors (PFAs):</b>
Relevant healthcare experience
Ability to listen respectfully to diverse and differing opinions
Willingness to share insights and information about experiences in useful and constructive ways
Comfort speaking in group setting
Ability to represent both their own and broader perspectives
Flexibility and open-mindedness
Willingness to work in partnership and collaborate on solutions
<b>Recruitment Strategies:</b>
Identify previous PFAs with experience
Seek diverse members by outreach to community organizations serving hard-to-recruit populations
Engage clinicians and staff to recommend possible candidates, focusing on clinics that might be participating as a study site
Distribute recruitment materials broadly within the research network and to local health care partners
Ask other PFAs for suggestions
Utilize networks and organizations that work regularly with patient and family members (e.g., Patient Advisor Network, Institute for Patient- and Family-Centered Care)

**Table 2. Quarterly Patient and Family Advisor Meetings and Examples of Impact**

Agenda Items	Patient and Family Advisor (PFA) Insight	Overall Impact
Engagement Plan – Goals and Process Monitoring	Provided 13 ideas and feedback directly impacting the development of the Engagement Plan	Created shared goals and approaches to evaluate effective engagement
Patient and Care Partner Recruitment Strategies	Identified new methods and language to engage patients in study	Changed Research Project Partnership (RPP) agenda to incorporate suggestions, PFA-tested language incorporated in recruitment scripts
Patient Consent & Enrollment Phone Script	Simplified format, provided choice, integrated empathetic responses request/burden	Increased enrollment rates
Repurposing RPP Meeting to a Forum for a Larger Audience: Dissemination	Generated numerous updates for Forum, participated on planning committee	PFA co-moderator of the event
Improving Follow-up Data Collection	Development of initial, follow-up and mailer to encourage participation including patient/care partner-friendly language options	Improved survey completion at 6- and 12-month time points

**Table 3. Patient and Family Advisor Study Involvement**

Research Study Phases	Activities	Involvement of Patient and Family Advisors (PFAs)
Planning Nov. 2017- June 2018	<ul style="list-style-type: none"> <li>• Definition and measurement of key concepts and (i.e., goal-concordant care, secondary measures)</li> <li>• Engagement Plan development</li> <li>• Practice and patient inclusion criteria</li> <li>• Identification of important questions to ask patients and care partners in study</li> </ul>	<ul style="list-style-type: none"> <li>• Input as members of the Research Project Partnership (RPP)</li> <li>• Participation in all workgroups</li> <li>• Participation in quarterly PFA meetings</li> </ul>
Implementation: Training, Enrollment & Data Collection June 2018 – February 2021	<ul style="list-style-type: none"> <li>• Training and materials development</li> <li>• Delivery of training</li> <li>• Practice, patient, and care partner recruitment</li> </ul>	<ul style="list-style-type: none"> <li>• Input on training design and materials</li> <li>• Participation as trainers</li> <li>• Review of recruitment materials and processes</li> <li>• Suggested language for patient and care partner outreach</li> </ul>
Analysis March 2021-March 2023	<ul style="list-style-type: none"> <li>• Review of qualitative data</li> <li>• Review of quantitative data</li> <li>• Conclusions</li> </ul>	<ul style="list-style-type: none"> <li>• Participation in open-ended items coding groups</li> <li>• Review of preliminary quantitative analysis/interpretation</li> </ul>
Dissemination November 2021-ongoing	<ul style="list-style-type: none"> <li>• Two Annual Forums</li> <li>• Journal Articles</li> <li>• Conferences</li> <li>• General communication</li> <li>• Communication with study participants</li> <li>• Website</li> </ul>	<ul style="list-style-type: none"> <li>• Forum co-led by PFA</li> <li>• Review article outlines and drafts; contributed to article ideas</li> <li>• Serve as conference panelists and presenters</li> <li>• Review study communications</li> <li>• Contribute to mailing to patients and care partners with preliminary results</li> <li>• Contribute videos for website and ideas for other content</li> </ul>

methods to track progress, gain insights about what was working, and make any needed changes. This approach to monitoring and measurement demonstrated how engagement fit into the different phases of research and how it made major contributions to many aspects of the design and execution of the study. The different tracking mechanisms, examples of findings, and corresponding changes are described below.

**Feedback Surveys**

Quarterly surveys using a 4-point Likert scale (See Appendix B) were distributed electronically to all attendees, including PFAs, after RPP meetings via Survey Monkey® or Qualtrics XM. These surveys assessed the perception of participation, satisfaction with the level of engagement during the meeting, and ways to improve future meetings. We collected 186 responses, 60 from

PFA, after 16 quarterly meetings. As an example, the post-meeting survey included the question: “In the last RPP meeting, I felt: The research project was improved because of my participation.” Out of all participant responses, thirty-eight percent (38%) Strongly Agreed, 49% Somewhat Agreed, 10% Somewhat Disagreed, and 3% Disagreed. Based on early results, we increased our efforts to report back at each RPP meeting how ideas from prior meetings shaped the study and the number of positive responses increased over time. For example, we received feedback on how to improve web meetings for all participants. This resulted in higher utilization of polls, chat waterfalls, and breakout rooms to ensure participants were provided multiple methods to communicate in larger trial meetings.

**Annual Interviews**

Annual PFA assessments were conducted to create and sustain authentic research partnerships with PFAs and provide a protected time for reflection. These assessments identified what was working well and what changes might improve the experience and effectiveness of PFAs at both the RPP and PBRN levels. The results were reviewed to identify common themes relating to the impact of PFAs and future directions of the study. One significant change resulting from this feedback was the addition of quarterly PFA meetings 3 weeks prior to RPP meetings as a way to maintain a connection, allow more space for feedback and discussion, and prepare upcoming RPP meeting materials.

Annual interviews asked PFAs to reflect on the past year and their participation in meetings and workgroups, their

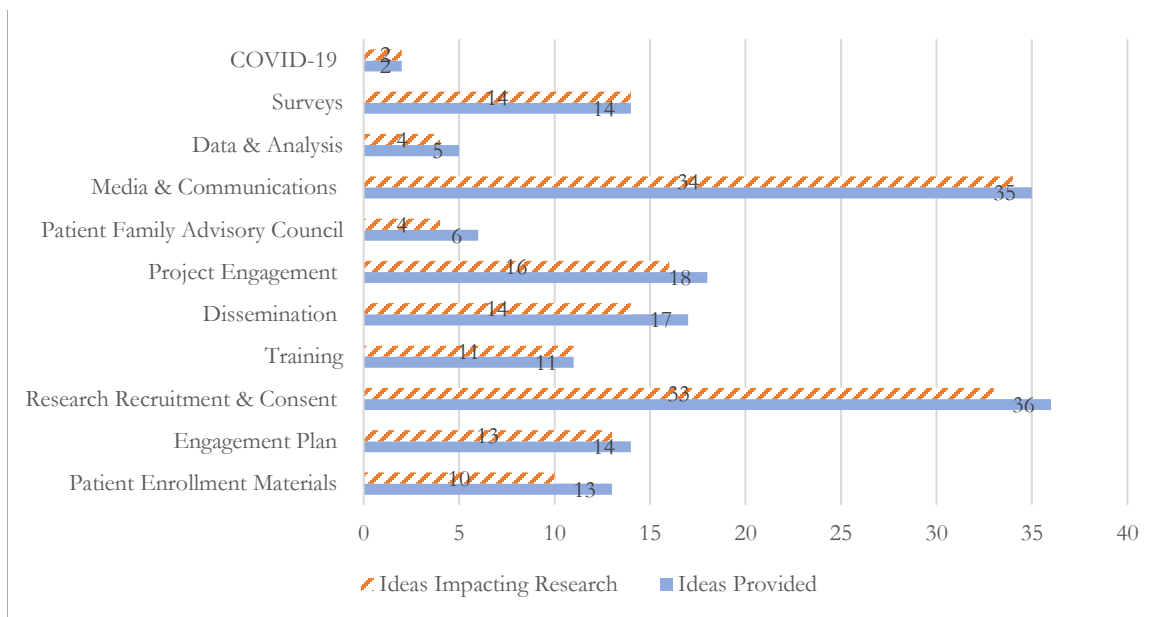
understanding of their role, and support received. PFAs then identified potential opportunities for meaningful activities and roles in upcoming years and provided recommendations for change and improvement (See Appendix C). For example, PFAs were asked, “What might the role of PFAs look like in the upcoming years of the project?” This allowed us to match personal interest and excitement about their participation with major trial meetings, academic presentations, and coding and dissemination workgroups, thereby maintaining long-term engagement.

The Engagement Manager conducted these interviews with PFAs at the end of each calendar year. Participation was optional and interviews were done via Zoom Videoconferencing using an open-ended, semi-structured interview guide. Interview responses were transcribed in real-time during the interviews. Interview transcripts were reviewed to identify common themes. The themes were outlined in a final report with supporting quotes from the interviewees.

**Impact Reporting**

Measuring the impact of PFA involvement was an important component of understanding the value of ongoing engagement and improving engagement efforts over the course of The Trial. Impact reporting was completed annually by the Engagement Manager and included a summary of PFA participation; a list of specific activities that invited PFA participation; and the number, description, and disposition of ideas generated by PFAs (See Figure 2).

**Figure 2. Patient and Family Advisor Ideas and Impact by Topics**



Each PBRN operations group and workgroup lead facilitator uploaded meeting minutes to designated, secure folders. Then, we created and maintained a spreadsheet to track PFA activities (See Appendix D) and ideas from each meeting. PBRN Directors and Coordinators and meeting facilitators documented suggestions and ideas in meeting minutes, which were added to this tracker by the Engagement Manager. We reviewed these routinely with the PIs and Coordinating Center staff to determine and document the disposition of each suggestion and its impact. The cumulative data from the entire project were analyzed by the Engagement Manager who grouped suggestions/ideas into topics.

Overall, PFAs participated in 259 activities, were present at 198 meetings, and spent 255.25 hours in meetings across project activities. PFAs generated 171 ideas and we incorporated 155 (90.6%) with direct impact on our research design and protocol. PFA ideas addressed a range of topics but were most frequently about Communications and Study Participant Recruitment as presented in Figure 2.

**Exit Interviews**

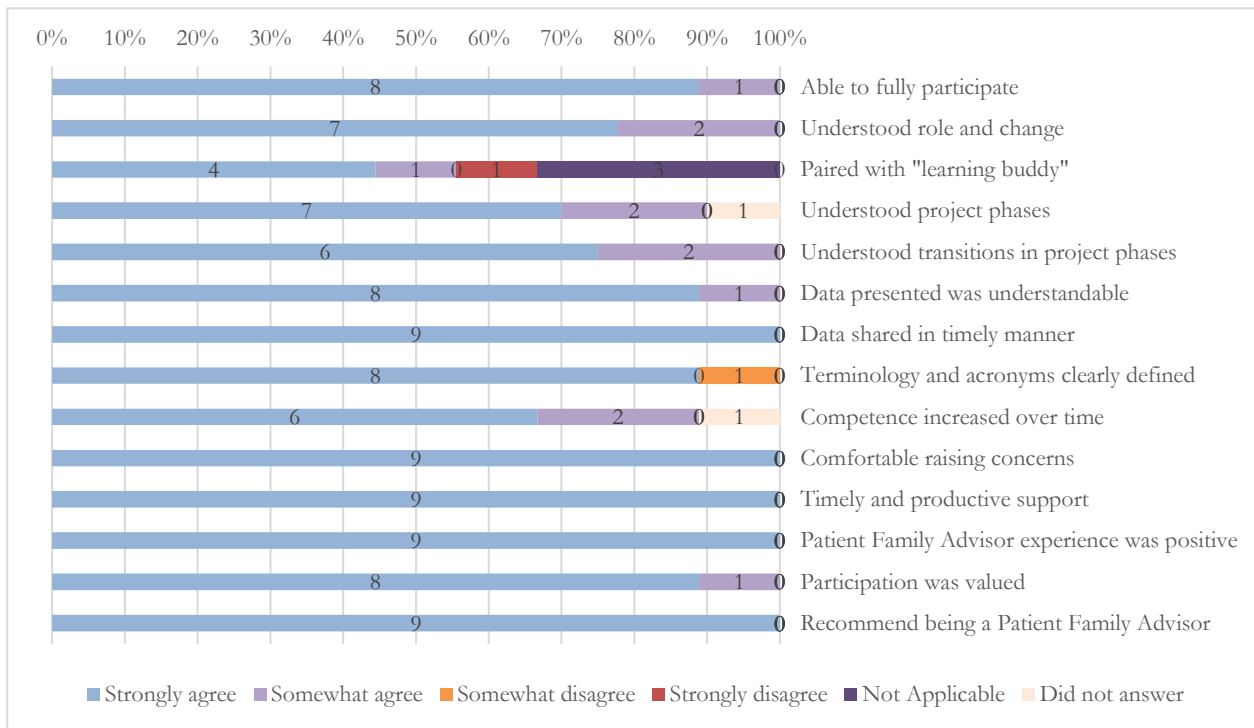
The Engagement Manager conducted nine key informant interviews with PFAs near the end of The Trial. While the intention of the annual interviews was to ensure continued involvement and sustain ongoing partnership, the purpose of the exit interviews was to capture lessons learned for

future projects as well as feedback about how well the research team responded to PFAs’ identified needs over the life of the project. Prior to the interview, PFAs were asked to complete an online survey (See Appendix E) indicating how much they agreed or disagreed with 14 statements using a 4-point Likert scale.

The interviews were conducted using Zoom Videoconferencing and followed an open-ended, semi-structured interview guide (See Appendix F). Interviews were recorded and then transcribed. Interview transcripts were reviewed to identify themes relating to PFA’s perceptions of their participation, their impact on The Trial, the support provided, and their recommendations for future studies.

PFAs were overwhelmingly positive about their participation for the duration of The Trial (See Figure 3). All interviewees endorsed that being a PFA was a positive experience, felt their participation was valued, and would recommend being a PFA in a research project to others. However, as indicated in Figure 3, not all PFAs understood their role at all phases of the study and felt their role would have been clearer if they had been more involved with the practices as well as the PBRNs and trial investigators. General challenges and lessons learned during The Trial will be summarized in the following section.

**Figure 3. Patient and Family Advisor Exit Interview Online Survey Results**





## Challenges and Lessons Learned

For PFAs involved in The Trial, the experience was overwhelmingly positive (100% in exit interviews). This is reinforced by the fact that they would recommend being a PFA to others. However, the achievement of this positive outcome required ongoing attention and improvement throughout the study. Not surprisingly, the sustained and meaningful engagement of PFAs in a research study spanning over five years and very different phases presented several challenges.

Specific challenges *and* our responses are described below.

### Challenges

The study attempted to include diverse perspectives and experiences among PFAs. The ongoing group of PFAs included men and women, both patients and family caregivers, representatives of urban and rural areas, people who were foreign-born, people for whom English was a second language, a range of experience with healthcare/diagnoses, and different levels of prior experience with research. In other ways, the PFA panel was more homogenous – socioeconomic and education (mostly middle class with college educations), age (mostly older), race (Asian, American Indian, and Native Hawaiian were not represented) and ethnicity (Hispanic not represented). This need in the healthcare field for greater diversity within PFACs and among PFAs has been highlighted recently as the result of a study conducted in US children's hospitals.<sup>14</sup>

An ongoing challenge centered on role clarification and PFAs effective integration *relevant to the needs of the study*. Initially, when PFAs joined the study, some aspects of the research could not be changed, for example, the research questions to be answered. This required clarification about what was “open” for input and what was not; some of these conversations occurred individually while others were incorporated into quarterly meetings with PFAs. Further, as individual phases of the study ended and others began (e.g., from planning to training, from training to data collection), the study's needs and opportunities for PFAs to contribute also changed. To avoid confusion and a mismatch between PFA expectations and trial needs, additional role clarification was provided at transition points between phases.

Recruitment, onboarding, and retention of new PFAs who joined after project initiation, to replace PFAs who withdrew, was problematic, especially in the Canadian PBRNs. This was exacerbated by language barriers for PFAs for whom English was a second language. Also, it was difficult to integrate new PFAs into an ongoing study using only virtual tools because in-person meetings were restricted due to the COVID-19 pandemic.

Another challenge was ensuring that investigators and research staff were skilled in engaging PFAs. As an example, in the early phases of the study, workgroups were created and PFAs were included as members. However, for some PFAs, the workgroup experience did not provide opportunities for meaningful participation, and their skills and input were not used effectively. Some PBRNs and PIs had not engaged with PFAs previously and needed support to incorporate PFA participation in PBRN operations group meetings. Additional training and support from the Engagement Manager were effective in helping less experienced researchers effectively integrate PFAs into the discussions and tasks.

The engagement of PFAs and PFACs at the local, clinic level, with support from PBRNs did not occur to the extent planned. As the study evolved, it became apparent that this was not a priority for clinics that were already stretched with many demands, including the impact of the pandemic. Many did not have PFACs; existing PFACs sometimes were not utilized for this research study. Other involvement of PFAs with clinic staff was not extensive.

Finally, like so many other projects, the engagement of PFAs during The Trial was impacted by the COVID-19 pandemic. After the kick-off meeting, no further in-person meetings were possible; virtual meetings were necessary for the duration of the project. Both study staff and PFAs experienced stress due to the realities of the pandemic. For example, one PFA had to terminate participation in the project due to family obligations while others missed some virtual meetings because of the new realities of working from home. Study staff were flexible in scheduling meetings and in providing follow-up to PFAs who could not attend.

### Key Learnings

Overall, we believe our engagement efforts were successful, as illustrated by this PFA assessment:

*I think this model (which I know was iterated and has been improved) – is THE model for patient engagement. All of the elements and components that you've built in are the model of mutually beneficial, mutually supportive, outcome-oriented patient engagement. ~Fourth Annual Interview, PFA 2*

However, this success required planning, significant effort, and dedication of resources. In our experience, the specific elements or components described below are necessary for effective engagement. These “lessons learned” are derived from the experience of the researchers and trial leadership, but also from the PFAs themselves who have shared their perspectives about engagement throughout The Trial. In addition to the description of each lesson, we have included illustrative quotes from interviews with PFAs.

1. Active encouragement and nurturing of PFA participation

Like all volunteers, PFAs want to be appreciated and valued for what they bring to a project or study. Throughout this study, the importance of PFA engagement was acknowledged in a variety of ways, including:

- Engagement was specifically built into The Trial plan at all phases.
- Study leaders articulated the value of engagement and acted upon it, e.g., the PI interacted directly with PFAs on a regular basis.
- Engagement was encouraged and supported at all levels, i.e., RPP, PBRNs, and individual clinics.
- Mechanisms were created to nurture and support PFAs – from the beginning of The Trial through the end (see the next two Learnings).

*The more we met, the louder the voices got. The more confident the voices got. The more comfortable people got with sharing. I think that really says a lot about the research team and how welcoming the research team has been of the patient voice. ~Fourth Annual Interview, PFA 6*

2. Preparation of PFAs for their role (initial and ongoing)

Initial onboarding and orientation are important but not sufficient, especially in a complex trial of this duration.<sup>15,16</sup> We found that **ongoing** clarification, communication and support about the PFA role was needed to increase confidence and participation. Initial outreach was done with each PFA recruited for the study. As described earlier, a formal, in-person, orientation session was held in Montreal, Canada in November 2017 where PFAs received background materials about the study and the PFA role. Quarterly PFA meetings provided opportunities to clarify the PFA role as the study moved from one phase to another.

*You have taught me and shepherded me along in this process so brilliantly and beautifully. I can now apply similar structural things to other projects. ~Fifth Annual Interview, PFA 2*

3. Ongoing mechanisms for inclusion, support, communication

Proactive communication and contact (with staff and peers) motivated PFAs and enhanced their engagement. The study built in a variety of mechanisms to do this, including outreach from study staff to PFAs, quarterly PFA meetings, monthly office hours with staff, and a monthly newsletter. The Engagement Manager organized annual assessments, offered the

availability of a “learning buddy” system, and provided one-on-one contact when needed/requested.

*There was never a time during the whole study that I ever felt disconnected. The meetings were always timely and kept you up to date and you never felt like there were huge gaps. ~Exit Interview, PFA 7*

*I know if I have a question, the communication is very open and very compassionate and that means a lot. ~Third Annual Interview, PFA 5*

4. Equality of PFAs with other stakeholders

Engagement of patients and families can be more tokenism than genuine involvement.<sup>17</sup> In healthcare, patients and families sometimes are invited to simply share their stories but are not regarded as true “partners” who participate in decision-making in all phases of a project or study. The Trial publicly strove to elevate the status of PFAs. For example, they were included in all key meetings (e.g., RPP) and workgroups. Their “voice” was valued in those groups. They also had key roles in study presentations – both internal and external.

*It is equal stakeholders from the researchers to the PFAs – everyone is on the same level, and everyone is respected in the same way, regardless of why they are there. ~Fourth Annual Interview, PFA 7*

*Hearing people share feedback and stories about the projects they've been part of and it's a lot of tokenism. I never felt like I was a checkbox of having a PFA part of the project. ~Exit Interview, PFA 7*

5. Range of opportunities for PFA involvement

While PFAs were selected for their “lived experience,” related to ACP, they also brought other life experiences and skills to the role (e.g., writing, advocacy, public speaking). It is important to provide a variety of effective ways for PFAs to be engaged at the level and in the tasks they prefer.<sup>15,16</sup> Over the five years of The Trial, PFAs had opportunities for engagement in different structures within the study (e.g., RPP, PBRNs, workgroups) and in activities during different phases of the study (e.g., from early training to final dissemination). This variety provided flexibility to “match” individual interests, skills, and availability to the needs of the study.

*I've been in the Cross-PBRN meetings, as well as the quarterly PFA meetings, and RPP meetings. I was working on the thank you for the participants and [the one] for the practices. I was also doing some of the [qualitative] data analysis of interviews with*

*the providers. It just feels like I am being useful, which is wonderful!* ~Fourth Annual Interview, PFA 10

6. Regular measurement and feedback regarding input/impact

While encouragement and support of PFAs is important to effective engagement, it is also critical to provide regular feedback about how their input is actually used and integrated into the operations of any study.<sup>15</sup> This creates trust and demonstrates that researchers truly value PFA contributions. The earlier section, An Improvement Approach to Engagement, has outlined the many ways PFA input/impact was measured and reported; this information was consistently shared with the PFAs.

*You let us know that what we did mattered – here are the results and here is how many people it affected.* ~Exit Interview, PFA 9

7. Engagement support and training needed for all involved, e.g., PBRNs, workgroup leaders

Just as effective engagement requires that ongoing training and support are provided for PFAs, support is also necessary for staff at all levels of a project or study.<sup>16</sup> As shared in the challenges outlined earlier, in a large and lengthy trial like this, the many staff and clinicians involved had a range of past experience in partnering with PFAs. Some were skilled and comfortable in the role; others were not and needed support. Consultation/coaching was built into the study for the Coordinating Center as well as PBRNs. In turn, PBRNs supported clinics in engagement activities.

*Bringing people [patients/PFAs, clinicians, and researchers] on in Montreal was a really good call. You are respectful and encouraging and if somebody was not struggling but needed a little bit extra support, you were there for them.* ~Exit Interview, PFA 9

8. Need for dedicated and sufficient resources (dedicated staff time, expertise, funding)

Effective engagement requires some commitment of resources, especially the allocation of staff time to provide training and support to PFAs and to ensure that communication is ongoing.<sup>15,16</sup> The availability of expert consultation/support as needed is also beneficial. Success requires allocating some budget to staffing, PFA compensation and costs associated with participation (e.g., travel).

*I know it takes the kind of funding you got from PCORI. I don't think every research project has the luxury of doing what we*

*are doing right now kind-of-thing. All of the elements and components that you've built in, to me, are the model of mutually beneficial, mutually supportive, outcome-oriented patient engagement.* ~Fourth Annual Interview, PFA 2

## Conclusion

The engagement of patients and families in research is becoming more common and is no longer optional for an increasing number of funders and programs. Meaningful engagement is rewarding but hard work. Success requires effort, resources, and humility. It also requires embracing a new normal that pushes us outside our comfort zone so that openness to change and improvement can enhance the research process. Authentic trusting partnerships between PFAs and researchers require consistent and sustained dialogue about how best to ensure that research adds value to the broader community. Systematic review of the engagement experience can inform needed changes and enhance these partnerships.

As a result of our experience, PFAs will be integrated into ongoing operations of our Coordinating Center. In this way, their voices can inform our thinking as we conceptualize future research studies. Additionally, we plan to provide more in-depth support to future research partner organizations (e.g., PBRNs, clinics) so they can better build effective and lasting partnerships with PFAs.

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## Appendices

### Appendix A. Advance Care Planning: Study Overview

## Advance Care Planning (ACP) for Adults with Serious Illness: Comparison of Two Models for Primary Care



### What we Studied

Discussion and planning for serious illness care can help patients identify what is most important to them and help assure they receive care that best matches their goals and values, such as spending more time at home or not being in pain. We conducted a research study about how to promote these discussions in primary care: where most people get most of their care most of the time. More information is available at the project website [PrimaryCareACP.org](http://PrimaryCareACP.org) and in the sources for additional information listed at the end of this document.

### Our Objective

To compare two models of the Serious Illness Care Program (SICP) in primary care: team-based SICP and individual clinician- focused SICP. In the individual clinician-focused model, a patient's primary care clinician was responsible for initiating and continuing conversations with patients and families about serious illness care planning, while in the team- based model, tasks were purposefully shared by a care team that includes a primary care clinician and one or more members from other professions.

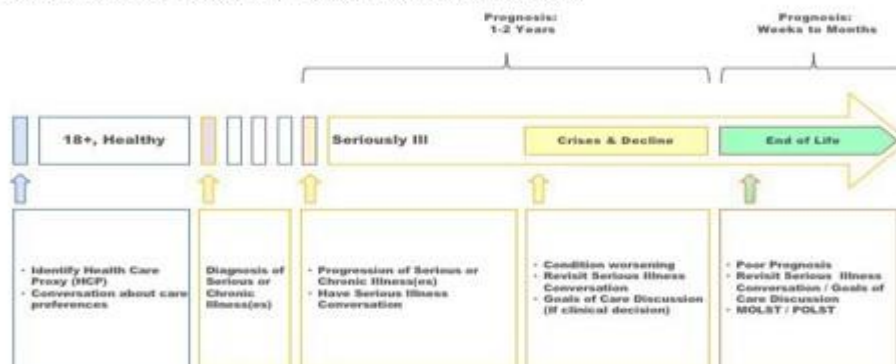


### The Serious Illness Care Program (SICP)

We used an established ACP program developed by Ariadne Labs. Effective ACP, particularly in the face of serious illness, requires more than a single conversation or completing a form. SICP is a comprehensive program. It includes training and adapting workflows. The foundation of SICP is the Serious Illness Conversation Guide, a structured approach that includes patient- and clinician-tested language.

### Introducing ACP

The image below is from a presentation about SICP. This graphic shows that talking about values and preferences can happen at several times in an adult's life. We focused on when a serious illness had progressed to the point that a patient's life or decision-making capacity was likely limited to 1-2 years.



**Advance Care Planning** = Planning in Advance of Serious Illness and End of Life Care  
**Serious Illness Care Conversation** = Talking about goal and values to inform plans for care for serious illness  
**Goal of Care Discussion** = Decision making in context of clinical progression / crisis / poor prognosis



## Appendices (cont'd.)

### Appendix A. Advance Care Planning: Study Overview (cont'd.)

#### Advance Care Planning (ACP) for Adults with Serious Illness: Comparison of Two Models for Primary Care



##### Meta-LARC: A Consortium of Practice-Based Research Networks (PBRNs)

PBRNs are organized groups of clinicians and practices that support engagement in quality improvement and research to answer community-based questions and improve health.

Participating in The Meta-LARC ACP Trial:

- 7 Meta-LARC PBRNs
- 42 Primary Care Practices (6 per PBRN)
- Recruitment target was: 30 Patients and Care Partners per Clinic/180 per PBRN



##### Participating Primary Care Practices

Primary care practices had to be affiliated with one of the Meta-LARC PBRNs and have an interest in ACP. The only exclusion is that they could NOT already have a standardized ACP program. Practices had to be willing to be randomly assigned to either of the two SICIP models. Once assigned, the practices agreed to implement SICIP. This included participating in training, identifying appropriate patients, assuring discussions happened, arranging follow-up as needed, and completing documentation so that patient values and preferences are known to family and other health care providers.

##### Eligible Patients

Eligible patients were over 18 years old with a serious condition who were receiving care at a participating primary care practice. Patients had to be community-dwelling (e.g., not living in a nursing home) and not already enrolled in hospice. Practices asked patients if they were willing to talk to a researcher and then referred interested patients to the study and a PBRN researcher contacted the patient to explain the study, obtain consent and collect data. Patients completed questionnaires after their initial serious illness conversation. Follow-up questionnaires were completed at 6-months and 12-months after enrollment.

##### Outcomes

The primary outcomes: 1) goal concordant care reported by the patient and 2) days spent at home in the prior six months. Secondary outcomes: additional patient, clinician/team member, and practice-level outcomes.

##### Our Timeline

The project launched in November 2017 and the main project period ended April 2023. We recruited and trained practices December 2017 through March 2019. Patients were recruited and enrolled January 2019 February 2021 with data collection through February 2022.

##### Additional Information

Totten AM, Fagnan LJ, Dorr D, et al. Protocol for a Cluster Randomized Trial Comparing Team-Based to Clinician-Focused Implementation of Advance Care Planning in Primary Care. *J Palliat Med.* Sep 2019;22(S1):82-89. doi:10.1089/jpm.2019.0117

ClinicalTrials.gov ID: NCT03577002

Ariadne Labs Serious Illness Care Program: <https://www.ariadnelabs.org/serious-illness-care/> Funded by:

Patient-Centered Outcomes Research Institute® (PCORI®) [Award](#) (PLC-1609-36277).



**Appendices (cont'd.)**

**Appendix B. Research Project Partnership Post Meeting Questionnaire – Short**

1. Are you a: (multiple choice – can only choose one)
  - a. Patient and Family Advisor (PFA)
  - b. Research Project Partnership (RPP) member
2. Did you attend the latest RPP meeting? (Yes/No)
3. Please rate how strongly you agree or disagree with the following statements: In this RPP meeting, I felt:

	<b>Strongly agree</b>	<b>Somewhat agree</b>	<b>Somewhat disagree</b>	<b>Strongly disagree</b>
<b>Able to fully participate</b>				
<b>Able to share my perspectives with the group</b>				
<b>The group listened to and took my ideas seriously</b>				
<b>That my contributions were valued</b>				
<b>The research study was improved because of my participation</b>				
<b>The contributions of PFAs as a group were valued</b>				
<b>Using the Zoom breakout rooms worked well</b>				
<b>Satisfied with how the break out groups report out went</b>				

4. What worked well at this quarterly RPP meeting?
5. What would you change for our next RPP meeting?

## Appendices (cont'd.)

### Appendix C. Patient and Family Advisor Annual Interview Questionnaire

1. Overall, how do you feel about your participation in the Meta-LARC Advance Care Planning (ACP) Trial?
  - Do you feel like an actively participating member of the trial?
    - If yes, what allowed you to be an active participant?
  - How you feel about your contributions and your ability to contribute?
  - Overall, would you rate your level of participation as ... (not enough, just right, too much).
2. How well do you now understand your role as a Patient and Family Advisor (PFA)?
  - Do you have any unanswered questions about your role?
  - Does the work we asked you to do match with your expectations?
  - As the trial has gone through different phases, have the changes made to your role as a PFA allowed meaningful participation?
    - Probe: What about the transitions through phases has worked well and what has been challenging?
3. Tell me more about how else you would like to be engaged or what kind of participation isn't necessary.
4. When thinking about communications or tools available from the study team, from the Practice Based Research Network and from Institute for Patient- and Family-Centered Care, are you able to receive adequate support in your role as a PFA?
  - What are your preferred ways to communicate with us? Has this changed?
  - Do you find the office hours and/or the newsletters useful?
  - What has worked best in the various meetings?
    - How can we improve web meetings?
5. What might the role of PFA look like in upcoming year 4 and the potential 9-month extension of the trial?
  - Where do you see the role of PFAs in the trial as we wrap up practice implementation?
  - How do you see your role in the trial evolving as we move to analyzing our results and sharing results with primary care practices?
  - What role could PFAs play in helping primary care practices continue an ACP program as the research is winding down?
6. Are you interested in collaborating on upcoming Meta-LARC ACP dissemination activities?
  - If so, what types of activities are you interested in:  
(i.e., oral presentations, posters, manuscripts for journal publication, popular press (newspaper, newsletters, radio, narratives/story telling etc.)
  - Would you be interested in participating on either a dissemination or analysis workgroup?
  - What skill(s) would you like or need support to develop for meaningful participation?
7. When thinking about the trial ending, what might be the steps taken to wrap up stakeholder participation?
  - Where do you see the role of PFAs in the trial as we begin to wrap up the trial?
  - How do you see your role in the future, beyond this trial, evolving as a PFA?
  - What role could PFAs play in keeping all advisors (i.e., clinicians, practices, external advisors, etc.) engaged in the final phases of the trial?
  - How can we continue to use your experience and expertise in future activities?
8. Would you be willing to share your mailing address with the study team and if so, what is it?



**Appendices (cont'd.)**
**Appendix D. Patient and Family Advisor Impact Tracking Instruction Sheet**

<b>Patient and Family Advisor (PFA) Demographics</b>	
<b>Purpose of this tab:</b>	<b>Track individual PFA contributions to summarize basic statistics</b>
Column A	Number PFA – number beginning with 1
Column B	PFA name – name of PFA
Column C	Start date – date PFA joined research study. If unable to identify exact date, use date of first meeting attended.
Column D	End date - date PFA withdrew participation from research study
Column E	Practice Based Research Network (PBRN) ID – name of PBRN, no PBRN affiliation record as At-Large
Column F	Clinic ID - name of clinic, no clinic affiliation, leave blank
Column G	Research Project Partnership (RPP) member – record as YES/NO
Column H	Workgroup member – name of workgroup assignment, not participating as workgroup member leave blank
Column I	RPP assessment survey – date of survey completion, no completion of assessment leave blank
Column J	Study orientation – date PFA was formally oriented to research study
Column K	Annual evaluation – date of PFA annual evaluation completion, no completion, leave blank
Column L	Special notes - special notes or comments relevant to the PFA e.g., attendance is sporadic because of current health issues; continue to reach out and check-in.
<b>Activity Tracker</b>	
<b>Purpose of this tab:</b>	<b>Record key meetings of researchers and PFAs, track hours and overall impact</b>
Column A	Meeting/activity – name of meeting or activity
Column B	Date – date of meeting or activity
Column C	# PFAs participating - number of PFAs in attendance
Column D	Hours - length of meeting in hours
Column E	Topic/focus – agenda research activity discussion items
Column F	PFA input received – PFAs provided input during meeting, record as YES/NO
Column G	Comments - special comments related to PFA input provided
<b>PFA Idea Tracker</b>	
<b>Purpose of this tab:</b>	
Column A	Deliverable – research activity receiving PFA input
Column B	Idea – idea(s) generated by PFA(s)
Column C	Change – result in change to protocol and/or research study design, record as YES/NO
Column D	Description of change – describe change to protocol and/or research study design
Column E	Positive impact – record as YES/NO
Column F	Additional notes - additional notes related to idea(s) provided e.g., follow up needed on idea, in-progress status of idea summarizing action taken to-date, reason idea did not result in positive change

## Appendices (cont'd.)

### Appendix E. Patient and Family Advisor Exit Interview Online Survey

**Instructions:** Please read each statement and indicate how much you agree or disagree with each statement as it applies to you personally. Your answers should be what is true for you and not just what you think the research team wants you to say.

If the statement does not apply to you, choose Not Applicable.

1. I felt I had enough information about the Serious Illness Care Program that I could fully participate
2. Information was provided that helped me understand my role and how it would change over time in the project.
3. I was paired with a “learning buddy” (another more experienced Patient and Family Advisor (PFA)) who helped support my learning about research and my new role
4. The different phases of the research project were described in ways I could understand
5. The process helped me know when a phase of the project was winding down and what would happen/be accomplished in the next phase
6. Data were presented to me in ways that I could understand throughout the study
7. Data about the results of the study were shared in a timely manner
8. Terminology and acronyms were clearly defined and did not create a barrier to my full participation on the project
9. My sense of competence to participate and contribute as a partner in the research project increased over time
10. I was comfortable raising concerns, questions or issues that could impact my participation or the project
11. The study leadership’s responses to my questions, concerns or issues were timely and productive
12. Being a PFA was a positive experience
13. My participation as a PFA was valued
14. I would recommend being a PFA in a research project to others

#### Response categories:

Not Applicable, Strongly Disagree, Disagree, Agree, Strongly Agree

## Appendices (cont'd.)

### Appendix F. Patient and Family Advisor Exit Interview Guide

Participation, support, and recommendations

1. As a Patient and Family Advisor (PFA), what has been a high point of your involvement with Advance Care Planning (ACP)?
  - Why was it a high point?
2. Which of your strengths and talents were called upon in this project?
3. As you think over the last 5 years of working together, what was your biggest “a-ha” learning moment?
  - How did this insight inform your continued participation?
4. We utilized several mechanisms to support and encourage your participation (*Montreal orientation, monthly newsletters, quarterly PFA meetings, office hours, etc.*). What did you find most effective and what about it helped you the most?
5. Describe a time during the Meta-LARC ACP project when you felt uncomfortable, unprepared, or least engaged.
6. As we think about working with new PFAs on new projects, what recommendations for change and improvement might you suggest?

#### Online survey responses:

Probes on any strongly disagree, disagree, or even an agree response:

- What change might move it to a strongly agree?
- What could we have done differently to better address this issue?