



Patient and stakeholder engagement learnings: PREP-IT as a case study

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Research supports growing affirmation of patient and stakeholder engagement (PSE) as an integral tool and highlights the need for further guidance on PSE best practices, frameworks, roles and responsibilities [1–3]. Even in environments where PSE is at the forefront, stakeholders may not self-identify as codecision makers, may not be able to specifically identify their contributions, may be unsure of their role expectations and functions, or – more pointedly – may report their role as tokenistic (superficially including a small number of people from a group to give the appearance of inclusion) [2,4,5]. With concerted and intentional effort; however, authentic and impactful PSE is achievable.

This commentary presents a case example of PSE in a clinical trial and the results of a small stakeholder-experience evaluation. PSE is foundational to the PREP-IT (A Program of Randomized trials to Evaluate Pre-operative antiseptic skin solutions In orthopedic Trauma) program's organizational structure and drives trial decisions and activities. PREP-IT stakeholders include patient advisors who experienced orthopedic trauma and/or surgery, and subsequent infection complications; professional-association representatives; a multidisciplinary healthcare team; and dissemination professionals.

Stakeholders codveloped the PREP-IT study concept and protocol following the 10-Step Framework [6]. The stakeholders, researchers and patients alike, engage in bidirectional learning as partners in advisory 'cores' and committees, which were developed to ensure a shared governance model, thereby, promoting cross fertilization and reciprocal communication. Cores are comprised of members with specific expertise in the subject area assigned to the core (e.g., patients with live experience, military personnel, infectious disease clinicians) [7]. The Patient-Centered Outcomes Advisory Core (PCOAC) was conceptualized and structured to ensure the patient voice was integrated effectively throughout the project's research continuum. As a result of the open communication between cores and committees, stakeholders with complementary expertise in trauma and dissemination joined the patient stakeholders on the PCOAC early on in the project.

During the course of the PREP-IT study, we experienced an evolution in the way the PCOAC stakeholders were engaged using the 10-Step Framework to guide the process of careful consideration to determine which approach would best elicit the stakeholder's perspective at each stage. Changes were made to meeting and engagement processes that came about due to PCOAC member's input. For example, the original approach was to conduct introductory meetings of the PCOAC, then move to a less formal schedule. It was immediately evident there was a productive synergy among the PCOAC members. In an effort to foster the collaborative environment, the study team pivoted and scheduled meetings every other month (bi-monthly), which PCOAC members attended unanimously.

We wanted to understand, from the PCOAC's perspective, why the members wanted to be part of a pragmatic clinical trial and what they believed would be missing from the project without their participation in these meetings. We conducted individual conversations with the five PCOAC members (three patients and two other stakeholders

Table 1. Overall insights from stakeholders.		
Theme	Illustrative quote	Respondent type
Group meeting approach: includes how the PCOAC operated or that participation was requested of them	“Meeting as a group seems natural; everyone participates”	Patient stakeholder
	“The educational component is most important; to have medical research clearly defined”	Patient stakeholder
Experience participating in the PCOAC meetings: includes details around participating in the PCOAC and whether they believed they were heard as partners in research, not just as subjects	“You build the relationship in the beginning so you are checking in, not checking a box; initial delivery (of the message) of why we subjects (are) equal partners in research”	Patient stakeholder
	“I never felt like a fish out of water.”	Patient stakeholder
	“You do not feel like you are at the little kid’s table at Thanksgiving.”	Patient stakeholder
Benefits to the PCOAC approach: includes the advantages of the PCOAC approach.	“It comes across loud and clear from multiple sites that they are listening to patient advisors”	Other stakeholder
	“When patients are involved, experts truly embrace that they are not the only experts; patients bring in the other half of the expertise to the equation.”	Other stakeholder
Disadvantages to not meeting: includes the loss or what would be missing if the current approach had not been adopted.	Stakeholders noted their participation in the PCOAC increased the likelihood they would participate in other activities outside of the study, “stepping outside the comfort zone”, which otherwise would not have happened.	Patient stakeholder

PCOAC: Patient-Centered Outcomes Advisory Core.

with dissemination and clinical backgrounds) regarding their experience to date. Here, we describe four themes identified related to the stakeholder-committee meetings: approach; experience; benefits; and disadvantages to not meeting. While our numbers are small, we believe the findings are useful to other researchers. We will discuss each in detail below. Examples of specific insights are summarized in Table 1.

Group-meeting approach

PCOAC members were asked why they wanted to meet regularly as a group. They reported that while voluntarily participation was requested, active participation was essential to be an effective team member and to stay apprised of study details. The frequency and intentionality of the meeting approach facilitated equitable contributions from the PCOAC members. The bi-monthly frequency of the meetings meant PCOAC members were routinely included in key discussions and brainstorming sessions, which was noted to contribute to the success of making stakeholders feel engaged. Without that frequency, participants noted that they might have felt: “like a token”, “less engaged” or “out of sight, out of mind”, The intentional approach to stakeholder inclusivity within the meetings built a platform for their voices to be treated as equal to other stakeholders at the table. An additional benefit of the group-meeting approach was to level-set knowledge for all members of the PCOAC by clearly defining medical and research terminology, and for project leads to set clear expectations for all members.

One example of an equitable contribution was a significant shift in the approach to study-participant follow-up. A PCOAC patient stakeholder explained that patients do not want to be ‘followed’, they want to be ‘listened to’ or ‘checked in on.’ The stakeholder further explained that patients want to know the study team cares about how the patient is doing rather than just approaching them for more data. Subsequently, in the PREP-IT program, the study team addresses preventing loss to follow-up through relationship building with study participants.

Experience participating in the PCOAC meetings

The stakeholders were asked about experience participating in the PCOAC and if members believed they were heard as research partners. Stakeholders reported it was clearly evident to them that stakeholder voices were heard. One stated they felt: “Passionately committed and heard, listened to.” PCOAC members reported they were reminded by study team members that their voices were important, ensuring that all stakeholder voices were treated as equal to other stakeholders at the table. When patients are involved, experts truly embrace that they are not the only experts. As one stakeholder reported, experts’ “knowledge is vast, but only half the knowledge. (The) patient is the other half of the equation.” PCOAC members resoundingly felt comfortable and welcome as partners in the research process. They believed their time commitment was worthwhile and felt a general sense of respect from the research team.

Benefits to the PCOAC approach

Stakeholders were asked about the benefits of meeting as a group. The model of a bi-monthly meeting kept PCOAC members engaged in a comfortable manner, allowing some stakeholders to transition from being seen as a chronic patient to being treated as an expert in the patient experience, and allowed some stakeholders to close the loop on healing, giving back and insulating against the “lows (e.g., anniversary of injury and surgery dates, set-backs in their own recoveries).” Stakeholders also reported it provided the ability to build off of each other’s input and a shared space for listening.

The stakeholders believed they were able to contribute equitably because of their past experience, but also because of the way that they were engaged; they were never treated as though they did not belong or their voices were not valuable.

Disadvantages to not meeting

Stakeholders were asked about disadvantages; that is, what would be missing if the current approach had not been adopted. Stakeholders reported that if the PCOAC approach had not been adopted, their participation in the project would have been passive rather than as an active member; they would have had less knowledge of the cases and study examples; and there would have been lack of cohesion. Additionally, stakeholders noted that their participation in the PCOAC increased the likelihood they would participate in other study activities, which otherwise would not have happened.

Conclusion

Knowledge regarding patient and stakeholder experiences with engagement in research can help improve the science of engagement and establish best practices, which are currently sparse. We found that intentional and routine interactions catalyze meaningful PSE. Eliciting feedback from stakeholders should be considered when seeking to understand a project’s stakeholder engagement activities successes and challenges. The PREP-IT program’s experience illuminates how genuine and frequent activities can be leveraged to meet patients’ and stakeholders’ needs and elevate stakeholder engagement.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/ce-2020-0266

Author contributions

M Medeiros and TR Love analyzed and interpreted the conversations with the PCOAC members. M Medeiros, TR Love, GP Slobogean, S Sprague, EM Perfetto, N O’Hara and CD Mullins were major contributors in writing the manuscript. All authors read and approved the final manuscript.

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