

October 17, 2024

Health Literacy Month Webinar Series Q&A

Session 2: Creating and Sharing Plain Language Summaries – One Team's Experiences

During the October 17, 2024, webinar, several questions were posed by the audience. Following the webinar, the panelists responded to the audience questions that were not answered live. The following responses were prepared by the panelists from the Dana-Farber /Harvard Cancer Center: Timothy Erick, PhD, Christine McLaughlin, and Paula Steeves. Their responses are indicated by "DF Response"

These responses are intended to accompany the webinar recording. The responses reflect the opinions of the panelists and do not necessarily reflect the positions of Brigham and Women's Hospital, Mass General Brigham, Harvard University, or Dana-Farber/Harvard Cancer Center.

Below, the audience comment or question is quoted as written during the webinar. The panelist who commented on each question is indicated. In some cases, the questions and responses have been edited for clarity.

1. Did the team ever consult participants? Or people from the community that will be involved in the research studies? How were they involved? From the beginning?

DF Response: "Patients", as represented by Dana-Farber breast cancer patient advocates, have been involved from the very beginning of our program. The team does not consult directly with participants on the trials for which PLSs are prepared, nor do we consult directly with general members of the community. The breast cancer patient advocate group at Dana-Farber is quite large, and we have been able to solicit input from many patients who are part of this group, including those from underrepresented communities.

2. Question for patient advocates - how does your institution define your role? Do you get calls during the conduct of trials? If so, what kind? Do you define such calls as 'participant complaints' that then get reported at the time of CRs?

DF Response: The breast cancer patient advocate group plays many roles at Dana-Farber, especially involving research and providing the patient perspective. But we do not receive calls from participants on trials about their trials, nor do we make calls to them.

3. Can you comment on why you chose to focus only on living participants and not include, for instances, survivors of deceased participants?

DF Response: In terms of returning aggregate results directly to individual participants (Phase 3 of the DF process), we currently only have obtained consent from living participants about contacting them to return aggregate results. Survivors of deceased participants were not involved in the consent process, so we are currently unable to contact them to ask if they would like to receive aggregate results directly.

4. Do all DFCI trials make it into a peer-reviewed publication? If not, how do you return aggregate results to participants of trials that have not been published?

DF Response: It is our intention to publish the results of DFCI breast cancer investigator-sponsored trials in peer-reviewed journals. We are currently operating in a prospective manner, attempting to generate PLSs for trials for which results have recently been published.

5. Thanks for hosting this very helpful webinar and for all you have done to make this important initiative happen. Are you all discussing or moving towards publishing PLSs at the same time as the MS in a peer-reviewed journal or separately in a journal that publishes PLSs?

DF Response: Given that we are using the published manuscript as our starting point for writing the PLSs, our process involves publishing the PLSs as close to the manuscript publication date as possible. Over time, this is something we could discuss in the future.

6. How are you measuring success?

DF Response: "Success" can be measured in several ways, ranging from easiest to more time consuming: data measuring clicks on the Dana-Farber website; the response rate

and open rate to email communications to trial participants; and follow-up surveys to trial participants who received their trial's PLS.

7. **Did you struggle with keeping their page count and reading level low while also trying to appease the requests of the highly technical reviewers such as physicians and scientists who want to make the doc more complicated? If so, how do you address it?**

DF Response: Now that we have an established style and content guide, we generally do not struggle to keep the page count and reading level lower. Some trials are more challenging than others, particularly trials with an unusual design or multiple primary endpoints. In general, the PIs understand we are generating PLSs for a specific audience in which many members may have limited medical and scientific literacy. Thus, the PIs review the PLSs for accuracy of content but try not to change the writing too much.

8. **You mention that you take data from published manuscripts; in that case, shouldn't it be called PLSP- Plain Language Summaries of Publications? As for writing PLS, we mostly rely on CSR, CTD, IC, and protocol rather than published manuscripts.**

DF Response: The nomenclature is confusing because we have also seen PLSs of publications shortened to "PLS" within the published literature (Dormer et al. 2022. Res. Involv. Engagem.). So yes, technically we are writing PLSPs and calling them PLSs, which seems to be rather common. Our science writer also uses the informed consent and protocol in writing the PLSs.

9. **Could you share some common and/or constructive suggestions/comments received from Patient Advocates during the PLS creation process?**

DF Response: The Breast Cancer Patient Advocates' comments are often substantive content suggestions about clearly distilling the key results. Specific examples include: context about the disease - advocates often suggest crisp summaries of the current state of the disease (and how it might have differed when the trial started) because many cancer patients are confused about this; side effects - include those of interest to patients, even if not listed in the most common side effects in the published paper (e.g. hair loss); emotional sensitivity - word choices such as "high-risk patients" recharacterized as "higher risk"; and the "How has this helped" section is especially important in a trial with negative

results - advocates suggest wording that reminds participants of how their generosity has helped move research forward (correlative studies, future trials).

10. Is it helpful to reference the consent form when presenting the results to patients? The consent would be their existing hatrack to hang new information on, not the manuscript.

DF Response: The consent form is a very helpful resource for writing each PLS. We rely on it in conjunction with the manuscript and protocol.

11. The presentation of this process was wonderful, thank you! Have you all considered how would you go about offering these PLSs for someone who speaks Spanish for example? How would that process look like?

DF Response: Our current process for a trial involves writing each PLS in English. If the consent form for the trial is written in additional language(s), then we will translate the PLS into each of those languages. All PLSs are then published in the same location on the Dana-Farber website.

12. What tool is being used to identify the reading level of the PLS?

DF Response: We do not use a specific tool.

13. How many PLS are you usually working on in parallel? How many do you upload each year?

DF Response: The science writer tries to write about 3 drafts in parallel. Depending on how many breast cancer patient advocates are available at a time, they usually review 1-2 in parallel. Currently, our intention is to upload about 12 PLSs per year.

14. What graphic design software do you use? The graphics look very nice!

DF Response: Our professional graphic designer uses Adobe InDesign, and indeed does a wonderful job!

15. Do you normally do turnover of the reviewer pool, e.g., recruit new reviewers from time to time. I am just wondering if there is any consideration that when a reviewer has reviewed the PLS long enough, they would become an "expert" and may have slight bias down the line. :)

DF Response: We always seek new perspectives to avoid becoming stale and rotate in new volunteer lay reviewers, whom we train about our PLS process and provide a shadowing period. Our breast cancer patient advocates must wear two hats as reviewers: as "subject matter experts" who know enough to help frame complex content in a way that is meaningful to patients generally and as "lay readers" who know little about science or cancer.

16. If an interested lay person is looking at published manuscripts to learn about a topic, might the PLS be too much info for an intro? Is it or should it be required to submit a plain language abstract?

DF Response: Our goal in generating these PLSs is to describe the entire trial, including background, methods, results, and how the trial has helped move the field forward, within 4 pages. We found this to be the best method to convey all the necessary information within a relatively short document. During our optimization process, some of our PLS templates had a short, abstract-like summary on the first page. However, we decided that for most PLSs, the redundancy ended up making the overall document more confusing and added unnecessary length.