

Medical Communications and Writing for Patients

Editorial

This edition of *Medical Writing* offers a fascinating insight into the work being done by a group at Eli Lilly Japan, who describe their work with a patient advocacy group – from the start of the research right through to the publication of the results. We read a lot about all the positive aspects of working with patients (and clearly there are many!), but new ways of working do come with their challenges. This article is refreshingly honest and beautifully describes the concept, how the collaboration

was set up, and the challenges that the authors faced in bringing patients into the process.

I'm incredibly grateful to Aki Yoshikawa and colleagues for sharing their experience and knowledge so thoughtfully. There is no doubt that the positives of involving patients in our work far outweigh any challenges along the way, but it's wonderful to be able to learn from others so that we can pre-empt and overcome any difficulties more easily. And not least – it's very inspiring to read how the Eli Lilly group dealt with their challenges and overcame them.

SECTION EDITOR



Lisa Chamberlain James

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I hope that you enjoy Aki's article as much as I did, and in the meantime, stay safe and sane – enjoy the sunshine (if you have any!), and see you in the December issue!

Bestest,
Lisa

Involving patients in company-sponsored medical publications: Learning from collaboration with a patient advocacy group to engage patient authors

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Abstract

Patient authors can clarify the disconnect between patients and healthcare providers. This can make publications more relevant to the real world and support better shared treatment decision-making between patients and physicians. Eli Lilly Japan K.K. collaborated with a patient advocacy group (PAG) in Japan from the study planning to publications from 2021 to 2022. Our intention was to co-author publications with patient authors, but patients declined to be authors for the publications. It is vital to share the value and expectations of author participation with potential patient authors. This article

outlines the challenges in involving patient authors and how to overcome these challenges based on our experiences in collaboration with the PAG for company-sponsored medical publications.

Plain language summary of the article

More people are realising the importance of involving patients in the process of developing new drugs. One way to do this is to have patients contribute as authors in publications. Having patients as authors in medical publications can help bridge the gap between patients and doctors. It can make publications more applicable to the real world and help patients and doctors to make better decisions about treatments together.

Eli Lilly Japan K.K., a pharmaceutical company, worked with a patient advocacy group (PAG) in Japan from the start of our research until we published our findings. We aimed to include patients' views in the publications, making it easier for doctors to help patients decide on treatments together. Although we wanted three patients as authors in our publications, they didn't agree to be authors.

Working with the PAG, we found some challenges in getting patients to be authors. We

learnt that it is very important to be clear about our expectations and find patients who can meet those expectations. It is also important to explain why being an author matters and to make sure patients agree. Needless to say, good communication is key. We need to talk with patients about what we would like to achieve with them, give them enough time to think about it, and work together based on mutual understanding. By doing these things, we believe companies can successfully collaborate with patients as authors.

Introduction

The value of engaging patients throughout the drug development process is gaining greater attention.¹ An example of patient engagement is patient authorship in publications, and its presence and implementation are expected to increase.² It has been reported that patients and healthcare providers (HCPs) can have different opinions on diseases and treatment options.³ Patient authors can clarify the disconnect that exists between patients and HCPs, and make publications more relevant to the real world.² Therefore, it is increasingly valuable to involve patient authors and reflect patient perspectives in publications. In fact, in recent history, pharma-

ceutical companies have published manuscripts co-authored with patients in peer-reviewed journals that incorporate and reflect patient perspectives.⁴⁻⁵ Furthermore, many patients and caregivers want to know about new treatments, be better informed about treatment options, and have a voice in making treatment decisions.⁶ Evidence shows that patient involvement in their own care leads to better treatment outcomes.⁷⁻⁸

Eli Lilly Japan K.K. (ELJ) has taken the initiative to actively involve patients in publications as part of the Patient-involved Publications (PivoP) project. The vision of the PivoP project is that publications are made more relevant to the real world and contribute to better patient-physician shared treatment decision-making by including patient perspectives. This aligns with the pharmaceutical industry's direction of empowering the voices of patients in the development of medical treatments.⁹ In this article, we will discuss ELJ's patient-involved publication initiatives, especially patient authors, and share what we have learnt from our experiences in collaborating with a patient advocacy group (PAG) for company-sponsored medical publications.

Co-creating publications with a patient advocacy group (PAG)

ELJ's first collaboration with a PAG from study planning to publications

ELJ conducted an observational study by means of a web survey on early-stage breast cancer (EBC) patient adherence to treatment, and the data were published in 2022.¹⁰ The purpose of

this study was to investigate adherence to adjuvant endocrine therapy (ET) as well as the factors affecting demotivation and motivation to continue adjuvant ET.¹⁰ Although the efficacy of ET for hormone receptor-positive breast cancer has been established, it is not easy to complete treatment because the recommended duration of treatment lasts 5 to 10 years.¹¹

To make the study results and publications more relevant to the real world, we wanted to reflect patient perspectives in the study protocol and survey questionnaire (hereinafter referred to as "study materials"), data interpretation, and publications (i.e., a manuscript and congress abstract/presentation). Furthermore, we created a plain language summary (PLS) as part of the manuscript to provide a summary of our article written in easy-to-understand language.¹²⁻¹³ We believed that a PLS could help physicians and other HCPs acquire a better understanding of the data more quickly.

We collaborated with a PAG in Japan (NPO Breast Cancer Friendship Association Kirara) to reflect patient perspectives in the study materials, data interpretation, and publications including a manuscript PLS. This was ELJ's first collaboration with a PAG from the study planning stage to publications. Figure 1 shows what we planned to do, what actually happened, and the gap between them regarding patient involvement in this project (Figure 1).

What we planned

We planned to involve patients from the PAG in study planning and data interpretation, then co-

author the publications with these same patients to reflect patient perspectives in the study materials and publications.

What actually happened

Three members from the PAG were involved in the study planning of the observational study using a web survey, and their perspectives were reflected in the study materials and data interpretation. ELJ asked the three patients to consider co-authoring the publications (i.e., congress abstract/presentation and manuscript including PLS). While they had never previously authored a publication, one of them agreed to review the manuscript PLS and congress abstract/presentation. The patient reviewer pointed out medical jargon that was too difficult for the audience to understand, and in addition, suggested better visual aids.

The PAG appreciated the opportunity to become involved in these activities (i.e., study planning, data interpretation, and publication review) and being acknowledged in the publications. It was recognised by the PAG that the publications raised awareness of the importance of shared decision making between patients and physicians.

Gap analysis

None of the three patients who were involved in study planning and data interpretation agreed to be an author. The reasons for their reluctance were varied and included the following:

1. Not wanting to disclose their name
2. Not having sufficient time to contribute
3. Believing that others are more qualified to be an author.

It is vital to share the value and expectations of author participation with potential patient authors.

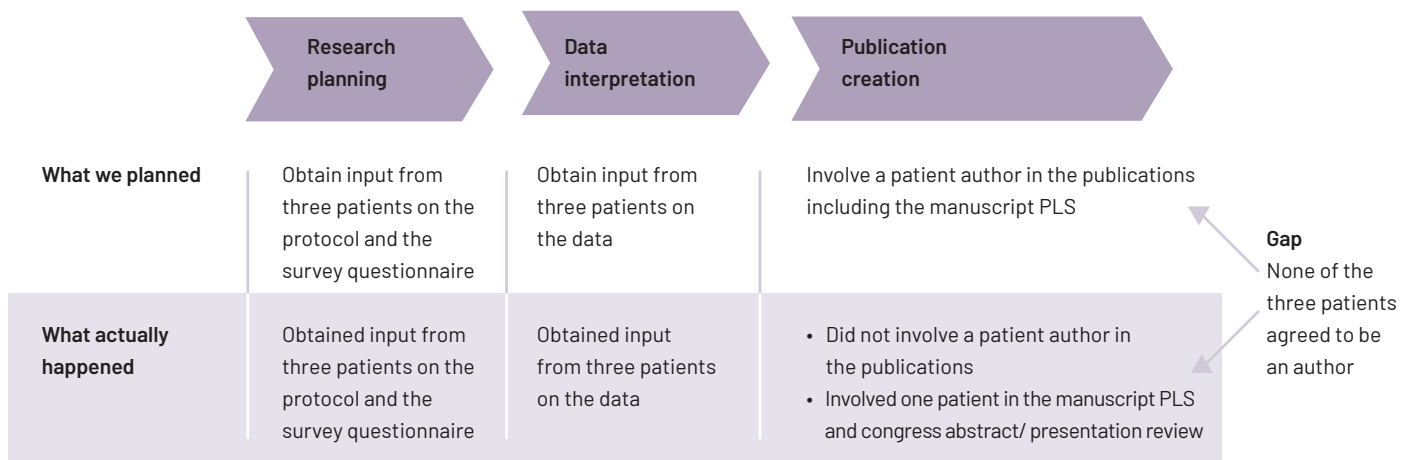


Figure 1. What we planned to do, what actually happened, and the gap between them in ELJ's first attempt to involve patients from the research planning stage to publication

Challenges in involving patient authors

Based on our experiences with the study on EBC patient adherence, we have identified the following challenges in involving patient authors.

Obtaining consent from patient author candidates

It is important for patients to fully agree on the value of their author participation before deciding to become authors. When we approached the patients who had never co-authored a publication, we needed to help them understand the essential significance of their author participation, then the authorship criteria¹⁴ and relevant rules.¹⁵

Since the three patients had been involved in study planning, we believed that they would prioritise the importance of incorporating patient perspectives in publications and be motivated to co-author publications. In addition, drawing from our practice with authors in general, we presumed that it was our responsibility to assist patients in comprehending the authorship criteria and relevant rules. This is why we focused more on explaining the authorship criteria and relevant rules rather than sharing and discussing the importance of reflecting their perspectives in publications, why we wanted to co-create publications with the patients, and what we hoped to achieve by involving patient authors.

Moreover, we did not fully consider the priorities from their perspective and what would deter them from being involved in publications as authors. Our approach could have considered how patients who had never been involved in publications would feel when they were approached to become authors and the impact on their daily lives. For example, we did not thoroughly take into account the fact that becoming an author would be a public announcement of their illness and how they would feel about it, as their name would be published, or that their physical and mental conditions might not allow them to participate as an author.

We should have spent more time and effort on reaching a mutual agreement and how to address patients' concerns about authorship and relevant rules. In fact, the PAG president commented that when we proposed the patients to participate as authors, she observed a similar lack of communication that sometimes happens between patients and physicians in daily clinical practice.



Clarifying our expectations for patients when we ask them to become involved in publications

We offered authorship of the publications to patients who had been involved in study planning and data interpretation. We asked the PAG president to refer patients from different backgrounds because patients with EBC have different demographic characteristics (e.g., age, work status) and we wanted to reflect the lived experiences and perspectives of multiple patients. However, we did not properly convey what we expected patient authors to do. This unfortunate oversight was due to the fact that we did not realise that our expectations for patients could be different for the study planning compared with publications.

When the three patients declined our proposal to be authors, we realised that what we wanted to achieve with patients was different for study planning and publication authorship. For study planning, we wanted to involve patients with lived experiences, and it was not mandatory for them to have motivation to be involved in the publication-related activities. However, for publications, we needed to involve patients who had an understanding and willingness to be involved in publication-related activities and who were willing to provide input on behalf of the patient community. We should have clarified our expectations for patient authors before requesting that the PAG president introduce patients to us.

How to overcome the challenge of involving patient authors

Sharing the value of patient author participation

It is important that patients fully understand, and empathise with the value of their author participation, and are motivated to become authors when we propose authorship to them. The main value of patient authorship is that patients have insight into their disease that even clinicians and pharmaceutical companies may be unaware of.¹⁶ Patient author participation clarifies areas of a disconnect between patients and HCPs.² As a result, patient perspectives help publications to become more relevant to

the real world and support patient-physician shared treatment decision-making, which will hopefully improve patient outcomes.

When approaching candidate patient authors, it is vital to first fully share our view of the significance and value of patient author participation with them, aiming to gain their understanding, and to provide a clear description of the author's role in concrete terms. Only then can we carefully explain the authorship criteria and relevant rules. Moreover, it would be better to discuss with patient author candidates how their author participation can contribute to solving issues faced by their PAG community and patients in general, so that they feel aligned with, and motivated to, co-create publications.

In addition, we learnt that communicating closely and thoroughly with patients, allowing sufficient time for explanations and questions, and proceeding based on a mutual understanding are key considerations. We need to fully validate their concerns, being aware of what patient author candidates know and what they do not know about being authors on a publication.

Clarifying expectations for patient authors

We believe that it is important to clarify our expectations for patient authors before asking them to become authors. It is also necessary to convey our expectations to patient author candidates and to involve patients who can meet these expectations. Furthermore, we should take actions to help patients meet these expectations as a majority of patients have never co-authored a publication.

We have clarified ELJ's expectations for patient authors: those who have an understanding and motivation to be involved in publication-related activities and are willing to provide input

on behalf of the patient community. It is vital to communicate our expectations with patient author candidates and obtain their agreement to meet these expectations prior to starting the publication creation process. Table 1 details ELJ's expectations for patient authors and what we should do for them so that these expectations can be met.

Discussion/Conclusion

We collaborated with the PAG from the study planning stage to publications, with the aim of making our research results more relevant to the real world and supporting patient-physician shared treatment decision-making. We asked three patients to become authors of publications. They did not agree to this proposal, but one of them agreed to review the manuscript PLS and congress abstract/presentation. During the collaboration with the PAG, we identified several challenges to involving patient authors and how to overcome them.

As indicated above, it is important to clarify our expectations before asking candidate patients to become authors, then to involve patients who

can meet these expectations. It is vital that we share our view of the value of author participation and that they understand that value. In addition, we learnt that taking steps to help them meet those expectations is a key factor. It may be better to approach patients who already have sufficient knowledge and experience to become a patient author (e.g., a PAG president) because they are likely to understand the importance of patient involvement in publications and to meet the expectations for patient authors (Table 1). Needless to say, it is also important to communicate closely and thoroughly with patients, allowing sufficient time for explanations and questions, and to proceed on the basis of mutual understanding.

We believe that addressing the above points will help medical writers to successfully collaborate with patient authors. That said, this article is based on a limited number of projects in ELJ. As such, there may be other challenges that have not yet been identified. We will continue involving patients in publications to make publications more relevant to the real world and valuable. We hope our insight will help

readers create publications with the invaluable contributions and perspectives of patients, which will contribute to improving patient outcomes.

Authors' contributions

AY drafted the article, and all authors (AY, AI, MH, and YK) were engaged in revising it critically. All authors read and approved the final version of the article.

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Disclosures and conflicts of interest

All authors (AY, AI, MH, and YK) are employed by ELJ and are minor stockholders of Eli Lilly and Company. This article was funded by ELJ.

Table 1. Eli Lilly Japan's expectations for patient authors

No.	Criteria	What the company should do so that patients can meet these criteria
1	Be able to understand and accept the company's publication activities and recognise the value of patient author participation in the publication for which the patient will be an author	<ul style="list-style-type: none"> ● Fully communicate the value of patient author participation which would allow patients and the company to reach a mutual understanding ● Give sufficient time to patient author candidates to consider if they would like to become patient authors ● Answer questions from patients
2	Have sufficient knowledge, experience and understanding of the disease and general roles of publications to become a patient author	<ul style="list-style-type: none"> ● Provide relevant information to help patients increase their knowledge of the disease and publications as needed ● Answer questions from patients
3	Be able to understand the rules of authorship and publication guidelines ¹⁴⁻¹⁵	<ul style="list-style-type: none"> ● Explain authorship and relevant international rules in plain language ● Answer questions from patients
4	Be willing to share their own opinions to improve the publications	<ul style="list-style-type: none"> ● Explain the research plan and data ● Schedule a meeting with patient authors as appropriate to explain the publication content and the key points of the review ● Notify patients in advance of the review periods ● Answer questions from patients when they review publication drafts
5	Be able to independently confirm that their opinions are reflected in the publications and point out any issues that are not reflected in the publications	
6	Be able to secure the time to review publication drafts and to review the publication drafts as scheduled	



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