The Oncologist®

Commentary

Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer

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A cancer diagnosis can be devastating for a patient and their family. Although advances in cancer research have given patients more treatment options, resources are needed to assist patients in understanding their diagnoses and navigating treatment options. Patients are often left wondering where to start and where to go for understandable information, because medical terminology, specifically terminology surrounding cancer diagnosis and treatment, can be complex. Although many people in the health care industry are trying and address this very problem [1], the communication barrier between the health care provider and patient still exists [2]. One way to improve existing communication barriers is by identifying methods to convey patient-friendly language to those who are making critical health care decisions—the patients themselves.

Oncology is a therapeutic area in which it is vital for patients to be aware of and understand treatment options so that they can make informed decisions and feel empowered to share in the treatment decision-making process with their oncologist and other care givers [3]. We have increasingly learned from patient engagement and U.S. Food and Drug Administration (FDA) public workshops that many patients have difficulty understanding trial terminology intended to convey a treatment's benefit and the harms that may be associated with its use. Traditional clinical trial efficacy endpoints, side effect profiles, and measures of symptoms, function, and other aspects of quality of life are important to patients, but limited understanding of many trial terms can hinder informed patient decision making. The evidence that forms the basis for approval of a cancer therapy may not be clear to patients, who must weigh the risks and benefits of a therapeutic option.

Examples of oncology terminology that may be unclear or not explained to patients are progression-free survival, overall survival, disease-free survival, and overall response rate. These terms are ubiquitous in cancer drug development but are nuanced and can be associated with complicated clinical trial designs.

Many physicians can communicate disease and treatment information well; however, given increasing time pressures in the clinic, it would be useful to clinicians and patients if a set of patient-friendly definitions could be generated for the most common drug development endpoints.

In helping patients navigate terminology, there is a role for oncologists, members of the pharmaceutical industry, patient advocacy groups, nurses, and pharmacists to collaborate on generating and communicating patient-friendly language. The first step is to work with patients and advocacy groups to gain a better understanding of the problem. Definitions of common terms can then be generated in an iterative dialogue between patients, health care providers, and drug development scientists. Once an agreed-upon set of patient-friendly definitions is generated by various stakeholders, these definitions can be communicated in multiple ways, including web resources, provider education (including pharmacists and clinicians), and patient advocacy groups. The use of multiple sources of information for patients may help to mitigate the challenge of increasing time pressures at the point of care.

The role of the patient advocacy community is increasingly important. Patient advocates are well positioned to use their unique background and knowledge to help patients navigate through the health care system. Many patient advocates are acutely aware of the latest policy developments from regulatory agencies as well as the pharmaceutical industry and have built important communication lines to patients in order to receive feedback and provide information and guidance. Unfortunately, many patients are not aware that cancer advocacy groups can be an important and available resource. This is especially true for medically underserved populations, including racial and ethnic minorities and individuals of lower socioeconomic status, as their ability to access health care is often more limited [4].

It is important to consider how we can improve the language we use with patients with cancer. A complete understanding of the risks and benefits of cancer therapies would allow patients and their families to make informed choices in their treatments. It is also important to be mindful of the patient as an individual and consider what specific terms

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need to be used when speaking with patients, as well as how and when to disseminate literature to patients.

The FDA is committed to making oncology clinical trial endpoint terms more understandable to patients and has engaged patients in multiple venues to garner input on patiently friendly definitions for clinical trial endpoint terms. Several common endpoints and patient-friendly definitions were publicly discussed with patients and advocates at a 2018 FDA workshop entitled "Partners in Progress" [5]. In collaboration with providers, patients, pharmaceutical industry, caregivers, and patient advocates, we intend to further this work with a goal to develop a glossary of "patient-friendly" clinical trial endpoint terms and definitions for patients and providers to use. For example, based on our interaction with patients, we have generated a draft patient-friendly definition of progression-free survival as "the median length of time after the start of this treatment that patients are alive while their cancer does not grow or spread." Further discussions are needed to ensure that these patient-friendly definitions are understandable to patients and caregivers. The glossary could be expanded in the future to include other clinical trial terms that patients have difficulty understanding.

Our common goal shared among those in drug development and clinical care is to help patients and bring a patient focus to navigating their complex treatment journeys. Regulatory agencies, payers, health care providers, the pharmaceutical industry, and patient advocates all need to work together to direct patients to available resources and craft patient-friendly language that can help patients make truly informed treatment decisions.

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References

1. Friedman AJ Cosby R, Boyko S. Effective teaching strategies and methods of delivery for patient education: A systematic review and practice guideline recommendations. J Cancer Educ 2011;26:12–21.

2. Graham S, Brookey J. Do patients understand? Perm J 2008;12:67–69.

3. Esposito L. Speaking up for patient preferences in cancer treatment decisions. U.S. News website. April 15, 2016. Available at https://health.usnews.com/health-news/patient-advice/articles/2016-04-15/speaking-up-for-patient-preferences-in-cancer-treatment-decisions. Accessed June 1, 2018.

4. Leading national cancer groups release joint statement to chart the future of cancer health disparities research. American Society of Clinical Oncology website. July 24, 2017. Available at https://www.asco.org/advocacy-policy/asco-in-action/leading-national-cancer-groups-release-joint-statement-chart-future. Accessed June 1, 2018.

5. FDA public workshop: Partners in Progress 2018 - Cancer patient advocates and FDA. U.S. Food and Drug Administration website. November 27, 2018. Available at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm600987.htm. Accessed June 1, 2018.