

ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

Section Editor: Mark J. Ratain, MD

A Patient Advocate Perspective on Oncology Drug Development

Deborah Collyar

President

PAIR: Patient Advocates in Research

Danville, California

H&O Can you discuss the background of patient advocacy? What is PAIR/SPORE?

DC There are many different types of patient advocacy: those focused on direct patient support, fundraising activities, government lobbying for financial support or policy decisions, and research advocacy. Research advocacy is primarily what I am involved with. Research advocates work within the medical research system to help make scientific work more relevant and timely for patients; advocates also learn what barriers exist in translating discoveries into results, and help resolve them when possible.

Cancer patient advocacy started in the early 1990s and represents individuals affected by cancer. Many advocates are involved in various cancer research committees. Advocates In Research (PAIR) was created in 1996 because of a need to change the research system by focusing more on results. PAIR is an informal international network of patient cancer advocates who have helped develop educational and strategic discussions between investigators and patient communities. Sometimes we participate in grant reviews, but we really focus on how we can work with researchers to make their work more relevant and effective for patients once the grants are distributed. A lot of work is done with the National Cancer Institute, the US Food and Drug Administration, the Office for Human Research Protections, government agencies such as the Centers for Disease Control and Prevention, and organizations like cooperative groups to ensure that cancer research policies and clinical trials are streamlined. Specialized Programs of Research Excellence (SPOREs) are grants that are implemented at institutions all over the country covering numerous types of cancer with which advocates are

also involved. The goal of SPOREs is to make sure that multidisciplinary groups of investigators work together to ensure that research leads towards a clinical application.

H&O How have patient advocacy groups influenced patient care in oncology?

DC Overall, there has been a positive effect. Early on, the goal was to change cancer from being a personal tragedy to a national issue, and this has been achieved. We also wanted to raise the level of funding in cancer research and to be involved in how money was being allocated. We wanted to have a voice in research and influence how results were being given to patients, and we have made considerable progress in all these areas. We have helped create a more positive environment for applied/translational research so that the focus is not just on basic science discovery, but also on how to develop these discoveries into useful answers for patients.

H&O What are the advantages/disadvantages of providing patients with study results? Has this practice been implemented in studies?

DC It is very important to provide patients with study results, specifically aggregate results. Patients who enroll in research think of themselves as research participants, which is essentially what we want them to be. They contribute in a major way by helping researchers learn more about their disease; therefore, they are interested in having study results in the first place. Providing these data helps move away from the guinea pig idea and allows patients to be part of something larger than just one patient at one institution in a study. Dr. Ann Partridge has conducted much research in this area. She and her colleagues administered a survey to HER2-positive breast cancer patients who participated in a phase III study of adjuvant chemotherapy with or without

trastuzumab (NCCTG 9831). Their findings showed that 95% of participants were glad they received study results.

When diagnosed with cancer, many patients seek out other people who have cancer. The more we can help educate patients who are enrolled in studies about their role and the importance of research, the more people will be receptive to the research process and provide information to newly diagnosed patients. The sharing of study results helps create a much wider base of people who can talk about research studies intelligently and promote research as well.

There can also be disadvantages to providing study data. One of the fears in the oncology community is creating additional anxiety for patients. In some cases, this may be true in patients who are given study results, and for this reason researchers and doctors need to be very careful in how the information is given. In Dr. Partridge's analysis, 23% of participants were more anxious about their disease after learning the study results. Negative study results were not found to have much impact on patients, although a few patients did feel distressed. Overall, there are some patients who may not feel comfortable knowing this information, and therefore it is very important to ask patients more than once if they want to receive study results. People feel anxiety whether they participate in a clinical trial or not, and allowing them to decide if they want results shows respect and fulfills the agreement made in most informed consent forms.

Efforts to improve patient-provider communication are under way. For example, Cancer and Leukemia Group B (CALGB) is currently working on creating study summaries that will present research results on their website. Eastern Cooperative Oncology Group (ECOG) has started to do this as well.

H&O For the US oncology community, what are the main challenges in cancer management today?

DC One of the main challenges in cancer management is to keep up with research findings. There are so much data available that it is very easy to fall behind. The plethora of available information illustrates the complexity in managing cancer patients today. Since we no longer employ a shotgun approach to treatment, many more factors have to be taken into consideration before a good management plan can be created for a patient's specific type of cancer. In the US, there is an abundance of new treatments, some targeted and some that are not, all of which are expensive. Thus, the challenge is not only how to fit the right treatment to the patient's can-

cer, but also how to provide that person with resources or places they can go to make sure they can pay for their treatment. Access and recruitment to clinical trials is also an issue. The US has many problems with access, including finding receptive providers in their geographical area, especially when a patient is trying to enroll in a clinical trial.

H&O What can be done to improve clinical trial development and patient care?

DC It is clear that we have to come up with better trial designs. We cannot keep using the same models that have been used for the past 50 years when we did shotgun chemotherapy. We are currently in a transition period, and patient advocates can be very useful during this phase, especially as we learn more about the value of biospecimen collection. Many cancer patient advocates are already involved in the cooperative group system, but they need to increase their presence in earlier phase studies, as well as at institutions and private practices. Because their point of view is experiential, patient advocates can bring awareness to issues pertaining to patients and participate in discussions early enough so that alternatives can be considered. This also provides advocates with the background needed to assist with recruitment efforts.

In terms of private practice, utilizing decision-making guides and questions is helpful. It is very important for the oncology community to keep in mind that patients are not a 'cancer'. They have life considerations that go into decision making. The faces of cancer are all different and each patient has a distinct life situation. Therefore, it is important for oncologists to help patients consider how treatment will impact their life and evaluate factors that are important in making educated decisions.

Everyone, whether or not they are involved with clinical trials, should help promote the idea that research is valuable. Once a patient is diagnosed with cancer, there are many stops along the path with specialists who can help emphasize research successes along the way. This is where we all can have an impact by explaining the benefits of research and the importance of this consideration.

Suggested Readings

Partridge AH, Wolff AC, Marcom PK. The impact of sharing results of a randomized breast cancer clinical trial with study participants. *Breast Cancer Res Treat*. 2008 June 10 [Epub ahead of print]

Partridge AH, Burstein HJ, Gelman RS, P Marcom K, Winer EP. Do patients participating in clinical trials want to know study results? *JNCI*. 2003;95:491-492.

Collyar D. "An Essential Partnership: Patient Advocates and Cooperative Groups." *Semin Oncol*. 2008;35:553-555.