

# Involving Advocates in Cancer Research

Jane Perlmutter,<sup>a</sup> Nancy Roach,<sup>b</sup> and Mary Lou Smith<sup>c</sup>

---

Advocates can play an important role in cancer research. In 2010, the National Cancer Institute (NCI) Advocate in Research Working Group (ARWG) defined a “research advocate” as an individual who brings and can convey a nonscientific viewpoint to the research process and can communicate a collective patient perspective through knowledge of multiple disease experiences. Experiences cited in this review are related to publically funded research. They, exemplify challenges and successes of advocate engagement and involvement in the cancer research process.

Semin Oncol 42:681-685 © 2015 Elsevier Inc. All rights reserved.

---

**T**he role of advocates in cancer research is not always clearly defined or understood by both advocates themselves and researchers. In addition, while many researchers are eager to engage advocates, they are often unsure of how to identify appropriate advocates and define expectations clearly. The goal of this article is to define the term “advocate”, review the role of advocates in cancer research, and to describe strategies to effectively engage advocates in cancer research.

## WHAT IS AN ADVOCATE?

The term “patient advocate” evokes many different images, including the following:

- the patient or caregiver who tells an inspiring story
- the survivor who provides peer support to newly diagnosed patients
- the people who participate in fundraising and awareness events
- patient advocacy organization staff and volunteers who lobby for research funding and/or favorable healthcare policy.

While few advocates are involved in the day-to-day work of conducting cancer research, many are

involved with groups that influence the direction of that work with activities such as the following:

- allocating research funding
- planning and implementing clinical trials
- translating and disseminating research
- informing research policy and oversight

Until recently, a clear definition of and role for this type of advocate did not exist in cancer research. The National Cancer Institute (NCI) Director’s Consumer Liaison Group convened the Advocate in Research Working Group (ARWG) in 2008. The work group was charged to develop recommendations on how to most effectively and consistently engage individual advocates in the research process to accelerate progress and benefit patients. The process engaged multiple stakeholders including advocates and researchers active in cooperative groups, SPORES and NCI advisory committees. In 2010, the ARWG final recommendations <sup>1</sup> defined a “research advocate” as follows:

- A research advocate brings a nonscientific viewpoint to the research process and communicates a collective patient perspective
- A collective patient perspective is created when a person has knowledge of multiple disease experiences and conveys this collective perspective rather than his or her own exclusive experience

The working group included advocates, NCI leadership and researchers active in extramural research, and the recommendations were ultimately approved by the NCI Director. As a result, the term “research advocate” has become widely used by advocates and researchers.

---

<sup>a</sup>The Gemini Group, Ann Arbor, MI.

<sup>b</sup>Fight Colorectal Cancer, Alexandria, VA.

<sup>c</sup>Research Advocacy Network, Plano, TX.

Conflicts of interest:

Address correspondence to: Jane Perlmutter, The Gemini Group, 507 N 5th Ave, Ann Arbor, MI 48104. E-mail: janep@gemini-grp.com

0093-7754/- see front matter

© 2015 Elsevier Inc. All rights reserved.

<http://dx.doi.org/10.1053/j.seminoncol.2015.07.008>

Many research advocates (referred to as advocates for the remainder of this article) become engaged in research due to a personal experience as a patient or caregiver. Some work for non-profit cancer advocacy organizations, and may or may not have a personal connection. While some formal training programs exist for advocates,<sup>2</sup> many advocates are self-taught. As a result, different advocates bring very different knowledge bases and skill sets to the research setting. This was confirmed by a survey of Cancer and Leukemia Group B (CALGB) advocates and researchers.<sup>3</sup> Survey results showed that researchers felt that advocate participation varied widely depending on the individual advocates. In particular, the researchers felt that some advocates were speaking “based on (their) own experiences rather than the majority of cancer patients”, pointing to the need to train advocates on how to speak from the collective patient experience as defined above. In addition, over half of researchers and advocates identified knowledge gaps as a challenge to effective engagement.

At the same time, there is general agreement that effective advocate engagement is important and beneficial. CALGB researchers defined the most impactful roles as disseminating research findings and providing a practical, patient-centered perspective on trial design. The ARWG found two broad categories of outcomes which were improved by effective advocate engagement:

1. Enhancing research
  - a. Advocate involvement improves clinical research feasibility by providing experiential knowledge of protocols’ impacts on patients.
  - b. Advocate involvement provides a perspective that can stimulate innovation and expand the scope of inquiry.
  - c. Advocate involvement serves as an immediate reminder of the need for research focused on patient benefit and outcomes.
2. Increasing public understanding and support of research
  - a. Advocate involvement increases public trust through enhanced transparency and accountability.
  - b. Advocate involvement helps break down barriers between the public and researchers.
  - c. Advocate involvement establishes a conduit for regular communication between the public and researchers.
  - d. Advocate involvement assists in disseminating research findings in clear and understandable ways.

- e. Advocate involvement helps other advocates understand and effectively communicate about science and research institutions.

An overview of research advocacy in cancer<sup>4</sup> published in 2013 identified the following key benefits of including advocates in the research process:

**Add a Human Face and Sense of Urgency to Cancer Research:** Most advocates have been personally affected by cancer. They bring a sense of urgency and provide a face – an immediate reminder – of why the science matters.

**Ensure Patient Focuses:** Researchers and advocates ultimately want the same thing — to eradicate the burden of cancer. Having an advocate at the table helps focus research on issues that are important to patients.

**Provide a Diverse Perspective:** Collectively advocates bring an experiential knowledge of the disease as well as a breadth of life and work experiences that can change the very nature of the conversation.

**Stimulate Discussion:** One of the most effective ways advocates contribute to research is by asking questions. Well-articulated, naïve or simple questions often result in robust discussions. Advocates are also well positioned to ask questions that may be more difficult for professional colleagues to raise.

**Expand Public Understanding of Science:** As advocates become better acquainted with the research process and the highly complex nature of the diseases we call cancer, they often more fully appreciate and convey the potential of research to their constituents.

Clearly there is a perception that effective advocate engagement can be helpful. The challenge is to define more specific roles for advocates in the research process and to engage them as true partners.

## THE ROLE OF ADVOCATES IN CANCER RESEARCH

The ARWG reviewed how advocates were engaged in research, and categorized their activities into four basic roles: advise, design, review, and disseminate.

*“ADVISE: Advocates engaged in advisory roles help develop recommendations or advise on strategic directions or broad policy issues. Advisory activities include participation on a formal advisory board or providing a critical perspective as part of a panel discussion at a scientific meeting.” (ARWG)*

Advocates engaged in advisory roles are generally part of multi-stakeholder groups, such as NCI

Advisory Committees<sup>5</sup> and committees, which set priorities for a larger group. One example is an NCI working group charged with reviewing the portfolio of National Clinical Trial Network (NCTN) trials and developing recommendations, which could be used to prioritize future NCI-funded clinical research. The working group, which included thirty-one extramural and nine NCI participants, had two research advocates. The advocates were actively involved in the discussions at the meeting and the development of the final recommendations.<sup>6</sup> These recommendations are being implemented,<sup>7</sup> and effect the NCTN Groups, the NCI Community Oncology Program (NCORP) Research Bases, the Scientific Steering Committees and the NCI.

Another example of advocate engagement with priority setting is with the Department of Defense (DOD). In 1993, the DOD began funding cancer research through the Congressionally Directed Medical Research Program.<sup>8</sup> The funding came through lobbying efforts of the breast cancer community, and the research program mandated the inclusion of advocates in grant review and priority setting. While this began with breast cancer, the program now includes funding for lung, ovarian, prostate, colorectal, and other cancers. Advocates are actively engaged in the DOD Integration Panels where they play a key role in setting research priorities and formulating Requests for Proposals.

Another example shows how advocates can help advise specific research questions. Eastern Cooperative Oncology Group (ECOG) advocates convened program managers from the Cancer Support Communities to identify symptoms most problematic to breast cancer patients. They determined that a difficult side effect was the arthralgias caused by aromatase inhibitors, which affect the quality of life of breast cancer patients and sometimes cause treatment discontinuation. The results of these focus groups were provided to the ECOG Symptom Management Committee. As a result, "E1Z11: A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms"<sup>9</sup> was launched and is close to being fully accrued.

*Design: Advocates engaged in design roles develop new or enhance existing programs or activities. Design activities include serving on a committee or panel involved in development of a new program or oversight of an existing program to provide the patient perspective or to identify patient barriers to implementation. (ARWG)*

Advocates in cooperative groups and task forces may be actively involved with trial design to identify potential barriers to accrual. The MATCH trial, an NCI initiative being implemented through ECOG, has a Patient Advocate Working Group, which includes advocates from multiple organizations. One of the proposed design elements was a drug

holiday for patients with stable disease after six months of treatment. There was strong scientific rationale for requiring drug cessation. However, the working group was concerned that patients with metastatic cancer might be unwilling to discontinue treatment which appeared to be working. The group developed a survey and used response technology at an ECOG meeting to query researchers, nurses and advocates about whether physicians and patients would support the drug holiday. There was an overwhelming response in favor of deleting the drug holiday from the trial design. The MATCH trial leadership was convinced by the findings and deleted the drug holiday.

Another example of design engagement is the role advocates have played in the development of patient-oriented tools. Preparatory Education About Clinical Trials<sup>10</sup> is a web-based educational tool designed to answer general questions about clinical trials. Developed by a research team<sup>11</sup> that included advocates, this web-based tool allows patients to pick questions that matter to them about clinical trials. In response, the tool delivers tailored videos to answer the questions. An advocate on the team convened two focus groups of advocates that helped the research team define the questions which the tool needed to answer.

Advocates can also be involved with development of informational resources to explain specific clinical trials to patients. For example, the I-SPY 1 Trial<sup>12</sup> (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis) required trial participants to undergo sixteen gauge core needle biopsies at four time points: before treatment, between 24 and 96 hours after starting treatment, after treatment, and at the time of surgical resection.

- Before treatment
- Between 24 and 96 hours after starting treatment
- After treatment
- At the time of surgical resection

As the trial was designed, advocates involved with the research team raised concerns that the burden of multiple biopsies which were not part of standard of care would create an accrual and retention barrier. They collaborated with the research team to design educational materials to train advocates to help patients understand the trial and improve trial retention.<sup>13</sup> While no formal analysis was performed to evaluate whether these tools were helpful, the final results show that of 237 patients accrued to the trial, only seven withdrew.

*Review: Advocates engaged in review roles evaluate and analyze research proposals and ongoing research activities. Review activities include participating in peer or concept review panels. (ARWG)*

Advocates are frequently members of committees which review research proposals, such as Scientific Steering Committees, study sections, DOD Peer Review Committees and Cooperative Groups. In addition, advocates may be part of Institutional Review Boards and Data Monitoring Committees. Formal review activity is confidential, so specific examples of activity are unavailable, although anecdotes are common.

Advocate engagement in review roles may be formal or ad-hoc. The patient advocate committee for the American College of Radiology Imaging Network (ACRIN) developed a structured format for advocates to use when reviewing concepts<sup>14</sup> and the completed form was given to the committee that made go/no go decisions. Advocates participating in formal peer review for NCI, DOD, and other funding agencies are often asked to provide written comment and scores, and also participate in discussions. However, not all review panels have a formal method of engaging advocates.

*Disseminate: Advocates engaged in dissemination roles interpret and communicate scientific information for nonscientific audiences. Dissemination activities include using scientific content to develop, edit, and/or distribute research findings to such audiences. (ARWG)*

Advocates engage in dissemination in many different ways. A researcher may seek out advocates to learn how to explain their work in a non-scientific way. For example, the NCI Office of Cancer Clinical Proteomics Research used feedback from advocates to help explain their work.<sup>15</sup> This interaction resulted in a lay-friendly resource<sup>16</sup> and an ability to communicate effectively with lay audiences. As part of the NCTN Alliance (previously three separate Cooperative Groups), advocates are involved with the creation of patient-friendly trial results, which are posted online.<sup>17</sup> Many advocates disseminate research findings directly to patients through web-based communities and social media. In addition, many patient advocacy organizations disseminate research results to their constituents.

As these examples show, advocates can play a role in the research team; however, their role is not always well understood by other members of the team. The CALGB survey discussed above showed that a substantial minority of CALGB researchers were unaware that advocates had a role in trial development (32.5%); improving accrual (28.6%); reviewing protocols for cultural appropriateness (52%); and assessing accrual barriers for specific trials (49.4%). The study issued a series of recommendations for clarifying and communicating the role of advocates within CALGB; however, the consolidation of the cooperative groups and change in leadership interfered with the formal implementation of the recommendations (personal correspondence, Roach).

Clearly, cancer research advocacy is still in its infancy with a relatively brief history, limited evaluations and few publications. In addition, there is no certification program, which makes identification and evaluation of advocate partners challenging. However, experiences such as the examples cited here and in referenced articles have created a growing body of knowledge that helping is to improve the effectiveness of advocates in research.

## HOW CAN RESEARCHERS HELP MAXIMIZE THE CONTRIBUTION OF ADVOCATES?

Effective advocate engagement requires that advocates are part of a collaborative research team. Establishing a framework that is likely to maximize the contribution of advocates is similar to developing collaboration with research colleagues.

First, expectations should be clearly articulated for the type of contribution that is sought. In establishing expectations, researchers need to identify the skills, experiences and style of working that are most likely to help advocates participate as part of the research team. Some that are often relevant include:

- **Collective Patient Perspective:** An advocate must have knowledge of multiple disease experiences and convey this collective perspective.
- **Basic Understanding of Scientific Method and Relevant Science:** An effective advocate brings a nonscientific viewpoint to the research process. Nevertheless, advocates should understand the non-linear, iterative nature of scientific discovery and be conversant in the relevant content and processes.
- **Excellent Team and Communication Skills:** Perhaps more than other team members, advocates must be comfortable engaging with diverse members of the research team, simultaneously ensuring that the patient voice is heard, while not monopolizing the conversation or thinking that the patient voice always trumps other considerations.

Defining expectations ahead of time may be challenging for researchers who don't work with advocates on a regular basis. Experienced advocates can help researchers in this effort. Experienced advocates can be identified by research colleagues, NCI's Office of Advocacy Relations and disease-specific patient advocacy organizations.

Engagement of advocates early in a project is also important, another finding from the CALGB survey and the ARWG recommendations. For example, advocates are often contacted when a trial is having difficulty accruing patients, with the hope that

advocates will be able to “get the word out” to interested patients. Often the problem has more to do with overly restrictive eligibility requirements, onerous procedures, inconvenient schedules, or other unattractive features of the trial that advocates might have pointed out before the protocol was finalized. Likewise, advocates are often contacted at the last minute before a grant application is due, asking for a letter of support and involvement with the research project. This is disrespectful to advocates and eliminates the possibility of the advocates providing meaningful input into the questions and methods of the research.

Also, listening to advocate feedback is important. As illustrated above, the MATCH investigators modified the protocol based on information provided by the advocates; however, advocate feedback is not always considered seriously. That’s not to say that advocates are always right about these issues; rather, when patient-centric issues are being decided, the advocate voice should be actively engaged, and concerns should be clearly addressed.

In addition, creating an environment where regular two-way feedback about what is working well and how both the advocates and researchers can contribute to making the collaboration even more effective is helpful. Advocates may not be familiar with the format of scientific discussions and may inadvertently be disruptive. For example, new advocates may be patients who have not had time to assimilate their diagnosis and/or understand and represent the range of patient experience. Their engagement may focus only on their personal experience (“how could this trial help me?” rather than “is this trial meaningful to patients?”). In situations where advocate engagement is not helpful, thoughtful feedback can be very valuable.

## CONCLUSIONS

Advocates play an important role in cancer research. Advocate involvement helps to focus research projects on outcomes that are important to patients, adds different points of view, and provides a sense of urgency. The perception that advocates always “get in the way” must be overcome. As with other team members, it is difficult to measure individual advocate contributions; they vary with both the goals of the group and the experience and traits of the members. Still, like other members of the teams, advocates’ participation in discussions improves the overall results.

Developing a pipeline of advocates is important and is currently done on an ad-hoc rather than systematic basis. Programs such as DOD provide training on how to review grants and emphasize

bringing new advocates in. The CALGB survey prompted the CALGB Executive Committee to explore issues such as advocate training and evaluation criteria. The advocates who serve on Scientific Steering Committees attend regular training webinars. Additional study of effective advocate engagement, followed by publication of the results, will help improve advocate identification and training.

## REFERENCES

1. <http://deainfo.nci.nih.gov/advisory/ncra/ARWG-recom.pdf>. Accessed March 12, 2015.
2. <http://www.breastcancerdeadline2020.org/get-involved/training/project-lead/>; <http://ww5.komen.org/GetInvolved/Participate/BecomeanAdvocate/BecomeanAdvocateinScience.html>. Accessed March 12, 2015.
3. Katz ML, Archer LE, Peppercorn JM, et al. Patient advocates’ role in clinical trials: perspectives from Cancer and Leukemia Group B investigators and advocates. *Cancer*. 2012;118(19):4801.
4. Perlmutter J, Bell SK, Darien G. Cancer research advocacy: past, present, and future. *Cancer Res*. 2013;73(15):4611–5.
5. <http://deainfo.nci.nih.gov/advisory/boards.htm>. Accessed March 12, 2015.
6. <http://deainfo.nci.nih.gov/advisory/ctac/0714/Sledge.pdf>. Accessed March 12, 2015.
7. <http://deainfo.nci.nih.gov/advisory/ctac/0714/Abrams.pdf>. Accessed March 12, 2015.
8. <http://cdmrp.army.mil/>. Accessed March 12, 2015.
9. <https://clinicaltrials.gov/ct2/show/NCT01824836>.
10. <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/pre-act>. Accessed April 2, 2015.
11. Fleisher L, Ruggieri DG, Miller SM, et al. Application of best practice approaches for designing decision support tools: the preparatory education about clinical trials (PRE-ACT) study. *Patient Educ Counsel*. 2014;96:63–71.
12. Esserman IJ, Berry DA, DeMichele A, Carey L, Davis SE, Buxton M. Pathologic complete response predicts recurrence-free survival more effectively by cancer subset: results from the I-SPY 1 TRIAL–CALGB 150007/150012, ACRIN 6657. *J Clin Oncol*. 2012;30(26):3242–9.
13. [http://cisncancer.org/services/docs/era\\_of\\_hope\\_2005.pdf](http://cisncancer.org/services/docs/era_of_hope_2005.pdf). Accessed March 12, 2015.
14. <http://www.acrin.org/COMMITTEES/SUPPORT/PATIENT/ADVOCACY.aspx>. Accessed March 12, 2015.
15. <http://www.cancer.gov/aboutnci/organization/oar/research-advocacy/success-stories/simplifying-nci-proteomics-messaging>. Accessed March 12, 2015.
16. <http://www.cancer.gov/aboutnci/organization/oar/CPTC-Brochure.pdf>. Accessed March 12, 2015.
17. <http://www.allianceforclinicaltrialsinoncology.org/main/public/standard.xhtml?path=%2FPublic%2FResults>. Accessed March 12, 2015.