Role of Advocates in Research: The Research Advocate Network (RAN) as a Model for Advocate Participation

After many decades of academia- and government-driven research in the cancer arena, patient advocates are beginning to play an influential role in the research process. Historically, advocates were not broadly included in research discussions and decision-making, or they were involved as token representatives of the patient community, often without the knowledge or ability to actually influence research. Although this trend has been reversing slowly, as cooperative groups and other institutions make efforts to incorporate advocates in research, many issues must still be resolved. Questions include: Are all patient communities represented by the advocates who currently participate in these venues? How knowledgeable are those advocates about the fundamentals of research and science? Even more importantly, how productive are the discussions between advocates and researchers, and can advocates actually influence the direction of cancer research?

Involving advocates in all aspects of cancer care has a huge upside. The patient advocacy movement has changed the face of cancer research by doubling National Institutes of Health (NIH) funding, assisting in the development of the innovative Department of Defense (DOD) research program, and lobbying federal and state governments to provide insurance coverage of new drugs and routine patient care costs in clinical trials and to create treatment appeals mechanisms. Patient advocates have also provided invaluable input into selected research processes, with increasing numbers of advocates within the patient community pushing for more inclusion in this realm. As the involvement of advocates in research expands, so does the need for training and support to educate and empower advocates to enhance their efficacy.

The Research Advocacy Network (RAN) is an advocacy organization that strives to involve patient advocates in all aspects of the research process. We founded RAN 3 years ago to involve more advocates in the design and conduct of cancer research and to equip them for effective interactions at these assignments. Although many influential organizations already existed in the advocate community, they have been focused on other aspects of patient advocacy such as fundraising, lobbying, policy issues, or increasing disease awareness. However, support is clearly necessary for those interested in research advocacy which is simply advocacy that focuses on the research process and incorporates the patient perspective. Research advocates work with scientists to help advance common goals, such as the development of more effective treatments for patients or the implementation of disease prevention initiatives.

By fostering interactions among advocates, researchers, and organizations, we believe the design and prioritization of research ideas can be influenced. Advocates must be armed with the tools necessary to positively impact all aspects of the research continuum, including the design, conduct, and reporting of cancer research.

Specifically, advocates involved with clinical trial design must be trained to ask the questions that are essential to patients. This helps to ensure that the
overall study is actually evaluating a scientific question of merit and that other issues are addressed that are important to the participating patients. Involvement can include ensuring that the required tests and procedures are relevant to the scientific study and that the eligibility criteria are not too restrictive, and even incorporating crossover designs to make the studies more appealing to patients.

To achieve this goal, RAN created the Advocate Institute to educate advocates on key elements of research, including the medical research system, the need for participant protections, and scientific concepts using new methods of learning and knowledge transfer. The Advocate Institute provides several tools, including a communication module to enhance discussions between researchers and advocates, to train advocates to effectively influence the design of research. Because advocates are often geographically dispersed and vary in their knowledge of the research system and scientific concepts, the Advocate Institute allows patient advocates to direct their passion toward more effective interactions with researchers through curriculum, on-site presentations, and online learning opportunities.

To gain different insights and comments on the design of specific clinical trials, RAN also facilitates focus groups with a cross section of patient advocate representatives and then reports the findings to the institutions developing the study protocols. For NCI’s TAILORx trial, which was activated in the spring of 2006, RAN conducted a focus group with advocates at the 2005 San Antonio Breast Cancer Symposium to gather input on key aspects of the study’s design. The focus group feedback did not change the research question asked, but was successful in changing certain elements of the design.

Although impacting the design of clinical studies is central to the research process, RAN also trains advocates to influence the actual conduct of research. Advocates can help ensure that patients are given informed consent documents that are thorough and clear, and that fully describe the study’s risks and alternative treatment options.

To explore these opportunities for advocates, RAN developed a pilot program to better understand the barriers for using advocates as community members of local Institutional Review Boards (IRBs). As part of this program, the organization conducted a focus group with 4 major research institutions to discuss attracting, training, and retaining community members. Based on focus group findings and additional research at the 2004 Annual Public Responsibility in Medicine and Research (PRIM&R) Conference, RAN created an IRB training program for patient advocates interested in becoming IRB members. To further disseminate its findings, the organization also conducted a training program for the IRB community members at the 2005 Annual PRIM&R Conference.

Because using patient tissue and blood samples in clinical research is important and often misunderstood, RAN created resources to educate patients and researchers on the importance of tissue acquisition in cancer research. These materials include a booklet for patients explaining the need for tissue, and an IRB booklet and slides with notes to be used by IRB staff and members.

Advocates can also impact the way research results are reported by urging institutions to provide results of clinical studies to participants, other advocacy organizations, and the public in a clear and understandable manner. Advocates can also work to ensure that all research results, both positive and negative, are shared with the public and that evidence supports new standards of care that emerge.

RAN addressed this opportunity by launching Focus on Research last year. This pilot program supported 15 patient advocates in preparing for and attending the 2005 American Society of Clinical Oncology (ASCO) Annual Meeting. The Focus on Research course consisted of 3 preconference presentations by well-known research professionals, a dinner reception at ASCO, and 2 postconference teleconference calls to share key learned information. Applicants for the Focus on Research program were selected based on specific criteria, including ability to communicate with patient populations and to disseminate the relevant research shared at the meeting.

RAN also developed patient-friendly fact sheets about recently released data findings. Four fact sheets were produced that detail the results of the Exemestane, Femara, Herceptin, and Avastin studies. The organization also developed newsletters, including one discussing research results, one designed for advocates and patients, and another targeted at health care professionals, especially community oncologists.

RAN recently piloted a lecture series in conjunction with the National Comprehensive Cancer...
Network to train breast cancer advocates on how to interpret research findings and how to understand what level of evidence is needed to change clinical practice. The lecture series consisted of 3 teleconference “webinars” with a panel of highly respected speakers. Each panel discussed topics such as what research findings are required for the Food and Drug Administration to approve a new therapy.

After working with advocates to influence the design, conduct, and reporting of research, RAN expanded its focus to include ongoing collaborations between advocates and cancer centers. One collaboration among RAN, the St. Louis affiliate of the Susan G. Komen Breast Cancer Foundation, and the Siteman Cancer Center developed an educational model showing how partnerships between local advocacy organizations and cancer centers can effectively attract and train research advocates. RAN also directs the advocate core at Indiana University’s Department of Defense Breast Cancer Center of Excellence and is currently developing a network of advocates and advocate organizations to support the university’s research.

Ultimately, we believe that patient advocacy groups must work both together and with the broad cancer community to build a network of advocates who can influence the design and conduct of research; to equip advocates with the scientific knowledge and experience necessary to engage in meaningful interactions with researchers; and to increase the collaboration between advocates and cancer centers. If advocates, researchers, and health care providers are successful in this work, they can ensure that cancer research is also patient-friendly.