



RESEARCH ADVOCACY NETWORK

Involving Patients in Cancer Research:

An Overview of Methods and Strategies Used By Research Advocacy Network (RAN)

Introduction

An important part of our work at Research Advocacy Network (RAN) is to advance patient care by encouraging and enabling cancer patient and advocate participation throughout the research process. We believe that patients and advocates can play valuable roles along the research continuum, from concept development to post-trial communications. Incorporating the patient voice in cancer research is intuitively important and has the potential to help research progress faster and further. Even post-research, patient and advocate participation can help smooth the transition of basic scientific discoveries into clinical practice.

At RAN, we have used a number of different methods to involve patients and advocates in the research process and beyond, to influence patient care. Each method we use, whether it is the structured interview, focus group, or survey, is standardized and based on established market research techniques. We have employed these methods to involve patients at multiple points along the research continuum.

Research Study Continuum



In this paper, we describe materials and programs designed by RAN to involve patients and advocates in cancer research and improve clinical practice. Each example describes three key points: 1) the method used to seek the patient’s understanding, opinion, or ideas; 2) the point along the research continuum at which patients were involved; and 3) important information gleaned from patient and advocate involvement.

As can be seen from these examples, involving patients and advocates in research using well-established, standardized procedures may benefit the research process by informing study concepts and designs, improving patient-investigator communications, enhancing research participation, and even improving patient care.

DESIGNING THE STUDY



TAILORx Trial

RAN participated in the design of the TAILORx (A Clinical Trial Assigning Individualized Options for Treatment [Rx]) trial, which had an enrollment goal of 10,000 women with early-stage breast cancer. The approach to designing this trial involved conducting focus groups with advocates and patients using a structured discussion guide, as well as structured interviews with advocate thought leaders. Information from these discussions and interviews was incorporated into a formal report and sent to the National Cancer Institute (NCI). This marks the first time that a report of market research reflecting patient and advocate input. These reports were considered by the study officials and resulted in changes to the study design that would inform the original scientific question.

Results of the focus groups and interviews resulted in a new, innovative design in which tumor tissue samples from all enrolled patients were tested using the Oncotype DX Breast Cancer Assay, but only patients with scores in the middle range were randomized to alternate treatments. The rationale for randomizing only patients in the middle range was based on previous research showing that patients with low scores on this assay benefit little from adding radiation therapy to adjuvant hormone therapy, whereas patients with high scores do benefit from the addition of radiation therapy to adjuvant hormone therapy. However, little is known about women whose scores on this test are in the middle range, from 11 to 25. Thus, in the TAILORx trial, only women whose scores fall in the middle range were randomized to the different treatment groups, allowing the low and high scorers to receive the treatment already known to be most beneficial to them.

The TAILORx trial recently closed to new participants, after enrolling more than 11,000 women — a number that exceeded the enrollment goal of 10,000. The interviews and focus groups provided valuable information on patient education materials, and illustrated that advocates and patients have similarities and differences; both groups are important sources of data for clinical trial design.

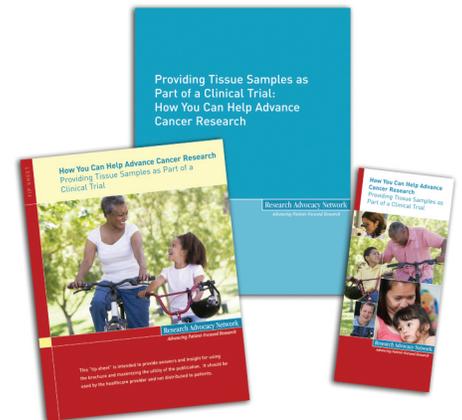
On the research process continuum, patient and advocate participation in the TAILORx trial planning and design took place at the study design phase. This represents yet another method of how the patient voice can be incorporated into cancer research.

Research Biopsies Communication Kit

RAN developed a communications kit designed to inform patients about providing biopsies exclusively for research purposes as part of a clinical trial.

Our first step in the development of this kit was to conduct structured interviews with members of the various groups involved in tissue research:

- Investigators who conduct the studies;
- Nurses who give educational materials to patients considering enrolling in clinical trials;
- Patients with various types of stage IV cancers.



Following the interviews, we used standardized reporting procedures to summarize the results. Several valuable lessons emerged from these findings that we then incorporated into the brochure. For instance, the term “biopsy” had a negative connotation for patients, implying that researchers would be looking for cancer. Thus, we used the terms “tissue samples” as opposed to “biopsies” in our materials.

From nurses, we learned that it is sometimes difficult to quickly find answers to the questions that are posed in the patient materials under the heading “Questions You Should Ask Your Doctor.” Nurses indicated that it would be helpful to have a tip sheet included with the materials that outlined answers to the questions because they, rather than the physicians, are typically the ones discussing the issues with patients. Moreover, because clinical trials often run for at least several years, members of the research team who work with patients may change. It was suggested that a tip sheet would help to provide consistency in communication and messages.

As a result of the interviews, we also packaged the brochure and tip sheet in a folder to keep the materials together in busy oncology clinics. Finally, we learned that researchers/clinicians who are successful enrolling patients in these types of clinical trials know how to talk with patients.

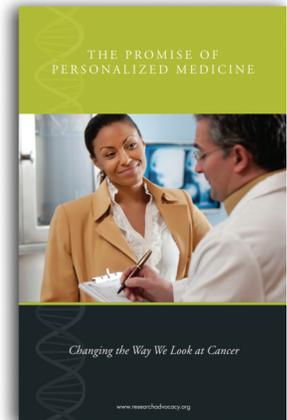
On the research process continuum, the RAN Research Biopsies Communications Kit may be categorized as helping to inform the research conducted. The Kit provides information that could influence a trial participant’s decision to provide tissue exclusively for research purposes. Such biopsies are critical to advancing our understanding of the basic mechanisms of cancer, how various types of cells respond to therapies, and how cellular responses relate to clinical outcomes.

CONDUCTING THE RESEARCH

Community Awareness on the Importance of Tissue Research

As part of a community outreach project designed to educate the public about the importance of tissue research, RAN recruited participants and hosted educational sessions in four different US cities. Each of the 30 to 65 attendees received a brochure to reinforce the message and expand the influence to family and friends.

Following each educational session, participants were asked to provide post session feedback by completing an evaluation form. From these post-educational session feedback forms, we learned that our brochure content was not well matched to the patient/public audience. The content for this brochure came from the tutorial entitled Genomics in Cancer, which was written for an advocate audience. To make the brochure more relevant and acceptable, the text was re-written, the title of the brochure was changed to "Personalized Medicine," and graphics and photos were added to make it more patient-friendly.



On the research process continuum, the RAN community outreach program on the importance of tissue research may be categorized as helping to enhance the research conducted. The participants in the RAN outreach program may eventually enroll in clinical trials or influence others to do so, who then may elect to provide tissue for research. This, in turn, advances the research conducted by increasing the amount of tissue available for research.

REPORTING THE RESULTS

Communicating Research Results Back to Participants

In order to better understand advocates' views on whether and how patients should receive the results of research studies for which they provided biospecimens, RAN conducted a survey of advocates who had participated in RAN-sponsored training programs. This standardized survey was sent to 100 advocates, and 32 surveys were completed and returned.

Results of the survey indicated that advocates believe that participants in clinical studies should have the opportunity to receive the results of genetic or other tests performed on biospecimens collected as part of a trial. Respondents were split on which healthcare professional should provide the research results, whether information on diagnostic discrepancies and incidental findings should be provided, or whether genetic counseling should be required. The highest agreement in the survey was on the question of whether participants should be able to decide whether they want to receive the research results, to which nearly all advocates (97%) responded in the affirmative.

The results of this survey are helping to inform how research results should be reported back to patients, thereby falling at the results reported point on the research process continuum.

IMPROVED PATIENT CARE

Survey of Advocate Knowledge and Perceptions of Comparative Effectiveness Research

As a prelude to the development of educational programs for advocates on comparative effectiveness research, we conducted a survey to assess current knowledge and perceptions in this area. The survey was sent to 200 advocates, of who 51 responded, comprising mostly females (92%) who had had breast cancer (61%). The structured survey included questions about positive and negative perceptions of comparative effectiveness research and its effects on healthcare.

Results of this survey showed that advocates held both positive and negative perceptions about comparative effectiveness research. Positive perceptions related to providing evidence-based

treatments across populations, comparing therapies and dosages, and reaching community-based physicians. Negative perceptions related to perceived restrictions on care that might result from such research, which RAN identified as an area in which education may be valuable.

Results indicated several additional key points, including the importance of using examples to explain what constitutes comparative effectiveness research and how it has been used. Advocates also noted that patients are unlikely to heed comparative effectiveness research until they are making treatment decisions. At that time, such research becomes relevant for them and represents a point at which advocates may introduce information that would be helpful to patients.

By evaluating the perceptions of advocates, the survey will allow RAN to design advocate training programs that explain how comparative effectiveness research is similar to and different from the clinical research trainees have been involved with to date. Advocates may then be able to help patients participate more fully in treatment decisions. On the research process continuum, this survey could be viewed as informing patient care, but could potentially affect all points on the continuum.

IMPROVED
PATIENT CARE



Information on B-RAF Testing

RAN also produced educational materials on testing for the B-RAF mutation in cancer patients. We first developed a draft tri-fold brochure that we presented to melanoma and lung cancer patients for their feedback.

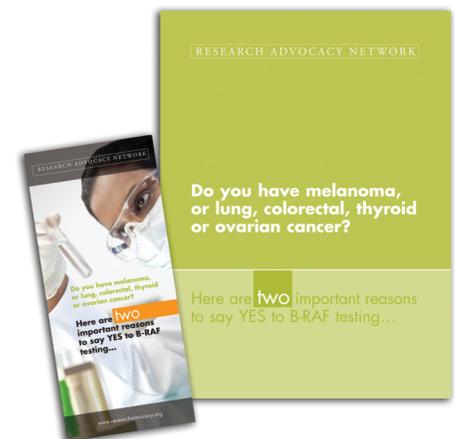
Feedback was solicited from individual patients in 30-minute interviews, which were conducted using a structured interview form.

From this feedback, we learned that patients do not want to know about the science. Instead, patients want to know the following:

- Why should I care?
- What does it mean to me?
- What will it cost me in dollars, time, pain and suffering?
- What questions should I ask?

We then revised the patient brochure to focus on these questions and re-tested it with patients. As with the research biopsies materials, we also had a guide for providers that was synchronized to the patient educational materials.

On the continuum, the B-RAF testing informational materials may be categorized as helping to improve patient care. Information obtained from B-RAF testing can be useful in providing a prognosis for certain cancers (e.g., how aggressive they are in the absence of any treatment) and their response to selected drug treatments. Receipt of information about what B-RAF testing means and what it entails – using materials that emphasize points deemed important by patients themselves – may lead cancer patients to undergo the testing, which could lead to improved care.



CONCEPTUALIZING
THE RESEARCH

DESIGNING
THE STUDY

CONDUCTING
THE RESEARCH

REPORTING
THE RESULTS

IMPROVED
PATIENT CARE



Summary

The examples discussed in this paper illustrate the multiple methods RAN has used to involve patients in the research process at different places along the research continuum. This involvement has resulted in key information and insights that have been incorporated into patient educational materials, study concepts and designs, and post-study communications. As noted in these examples, RAN uses well-established, standardized procedures overseen by a market research organization.

The following table summarizes the various RAN-sponsored materials and programs, including the methods used to obtain patient input, the point along the research continuum at which patients were involved, and some of the highlights or “key learnings” from patients.

EXAMPLES OF HOW RAN INVOLVES PATIENTS IN THE RESEARCH PROCESS		
Method	Point on Research Continuum	Key Learnings
TAILORx Trial		
Focus groups with structured discussion guide	Designing the study	<ul style="list-style-type: none"> • Didn't change the scientific question • Resulted in innovative trial design that was more acceptable to patients
Research Biopsies Communication Kit		
Structured interviews	Conducting the research	<ul style="list-style-type: none"> • The word “biopsy” is scary to patients • Answers should be provided for the “Questions You Should Ask Your Doctor” • Nurses are the ones who discuss study issues with patients in greater detail
Community Awareness on Importance of Tissue Research		
Structured evaluation	Conducting the research	<ul style="list-style-type: none"> • Brochure content not well matched to the patient/public audience
Communicating Research Results Back to Participants		
Structured survey	Reporting the results	<ul style="list-style-type: none"> • Participants in studies should have option of receiving results of biospecimen tests, patients should be able to decide whether they want these • We need more education for the public around the need for genetic counseling, the meaning and management of diagnostic discrepancies and incidental findings
Survey of Advocate Views of Comparative Effectiveness Research (CER)		
Structured survey	Improved patient care, potentially all points on the continuum	<ul style="list-style-type: none"> • Advocates hold both positive and negative views of CER • Concrete examples of CER and how it has been used are essential • Patients won't care about CER until they need to make treatment decisions
Education on B-RAF Testing		
Structured interviews	Improved patient care	<ul style="list-style-type: none"> • Patients find too much scientific information overwhelming and not useful • Patients want to know what the testing means to them and what the process will entail

RAN is actively following up on several of the projects noted in this document. We are also engaged in additional projects such as a focus group designed to determine how patients with metastatic breast cancer perceive the risk-benefit trade off of cancer therapies (e.g., effective dose vs. side effects) and how biomarkers affect their treatment decisions.

RAN seeks to partner with organizations and investigators who would like to incorporate the patient voice into their research. For more information please contact us via e-mail at info@researchadvocacy.org or at the address listed on our website: www.researchadvocacy.org.