Advocacy: The Patient Voice in Cancer Research

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NCI Physical Sciences in Oncology Network

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Introduction

Biomedical Engineer

- Mathematical Modeling
- Human Factors Engineering
- Aerospace/Hydrospace Physiology

- Diagnosed with breast cancer in 2004
- Diagnosed with skin cancer in 2010 and 2012
Introduction

**National Advocate**

**Physical Sciences–Oncology Network (2010–Present)**

Serves as the liaison between the public and the NCI’s Physical Sciences in Oncology Network (PS-ON), an innovative program that explores the physical laws and principles which shape and govern the emergence and behavior of cancer.
What are We Missing Here?
Why am I Here?

"Feel confident as a patient advocate for cancer research"
“The biggest challenges in accomplishing bedside science projects may not be scientific but humanistic… Address these elements as carefully as the scientific design of the study to enhance your chances of success.”

“One of the most striking changes in health care policy making over the past forty years has been the **growing attentiveness to the voices of patients**. The concept that the end users of health care—variously conceived of as patients, consumers, or simply “the public”—should be actively involved in decision making, in both therapeutic and economic domains, has gained widespread acceptance.”

Step 1: Communicate

Find a common language
advocate

verb: to speak or write in favor of, support or urge by argument; recommend publicly

noun: a person who speaks or writes in support or defense of a person, cause, etc.

https://www.dictionary.com/browse/advocate
How Does that Relate to Cancer?

“I remember when someone referred to a friend of mine as an advocate, she turned to me and said, ‘What is that?’

I think I said something like, ‘It is a group of like-minded people who want to help or speak for a specific group of people.’”
The Rise of the Patient Voice
Institutional Review Board (IRB)

- a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.
- priority is to protect human subjects from physical or psychological harm.

IRBs were developed in direct response to research abuses earlier in the 20th century. Two of the most notorious of these abuses were the experiments of Nazi physicians that became a focus of the post-World War II Doctor’s Trial, and the Tuskegee Syphilis Study, a project conducted between 1932 and 1972 by the U.S. Public Health Service on black men in rural Alabama.
**Brief History of Advocacy: Activism**

**AIDS Activists**

- HIV/AIDS activists of the 1980s set a model for all forms of health advocacy.
- Many scientists began to regard HIV/AIDS activists as having valuable knowledge that should be considered in decision-making about research, design, funding, and policy.
- Using the HIV/AIDS model of advocacy, other patient advocates became active in research arenas.
- Advocates were becoming key figures in decision-making about biomedical research, decisions that had important ethical and policy implications.

From writings by Rebecca Dresser, a lawyer and bioethicist from Washington University School of Law in St. Louis.
Brief History of Advocacy: Patient Groups

Rise of Patient Advocacy Groups

“Patient advocacy groups were born of a need to provide support and education for patients and to stimulate research for better understanding of diseases and their treatment... Because they represent patients’ perspectives, patient advocacy groups are considered important stakeholders in health-care policies, patient education, national guideline committees, and scientific research.”

Image from http://cisncancer.org/research/drug_development/stakeholders.html
Brief History of Advocacy: CDMRP

Department of Defense Congressionally Directed Medical Research Program (CDMRP)

1992: The United States Army Medical Research and Materiel Command funded research on breast cancer screening and diagnosis for military women and family members.

1993: Grass roots advocates led by the NBCC influenced public policy, which led to a full peer-reviewed Breast Cancer Research Program that is managed by the United States Department of Defense Congressionally Directed Medical Research.

1994: Roles established for patient advocates in both peer and program review.

Brief History of Advocacy: SPORE

Specialized Program of Research Excellence (SPORE)

SPORE Program May Never Have Been Launched without Advocates

Which has a certain irony, since, according to Ms. Collyar, the SPORE program may never have been launched without advocates.

“The SPORE program was originally conceived in 1991 by Brian W. Kimes, PhD, then-director of NCI’s Office of Centers, Training and Resources, and AndrewCharrodo, PhD, then-chief of NCI’s Organ Systems Coordinating Branch, but it had been shelved by then-NCI Director Samuel Broder, MD, who didn’t think it would work,” she said.

A group of 25 breast cancer advocates, led by the late Elenore Pred, one of the founders of the San Francisco-based Breast Cancer Action, went to see Dr. Broder, Ms. Collyar said.

Dr. Gomez added that the women were more activists than advocates in those days, and pressured Congress to make SPOREs a reality.

“Through the years, we’ve seen activists go from protesting to becoming patient advocates for research funding, and we [NCI] have been involved in a deliberate integration of qualified advocates into research programs, he said, noting that funding for SPOREs has grown from $20 million in 1992 to $128 million today.

https://journals.lww.com/oncology-times/Fulltext/2004/10100/SPORE_PART_ners___Advocates_Advance_Officially_in.16.aspx#pdf-link
“By advocating for or directly funding basic and clinical research, patient advocacy groups strive to contribute to an increased understanding of the pathogenesis of a disease, innovative treatments, and—ultimately—a cure. The goal of research funded by these groups is most often to increase awareness and improve patients’ lives, which implies a concentration on observational, clinical, and translational research. Members of support groups rate this scientific goal as the most important contribution of their organization.

Patient advocacy groups can also assist in identifying research questions that are important to patients; these often differ from the questions considered important by researchers and the pharmaceutical industry. Taking into account patients’ concerns in clinical research may reduce the number of unnecessary and sometimes useless studies.”
Five Aspects of Advocacy

The Worlds of Advocacy

© PAIR: Patient Advocates In Research
Political Advocacy

Fundraising

The Worlds of Advocacy

© PAIR: Patient Advocates In Research

Komen Dallas Race for the Cure, 2006
EXTENDING THE CENTER’S REACH

Genetic counseling, mobile mammography and other efforts connect with the community. A research finding more than a decade ago – that mutations in genes known as BRCA-1 and BRCA-2 could greatly raise a woman’s risk of breast and ovarian cancer – has lent new meaning to the old cancer genetics practice in the nation in terms of how many BRCA-1 and BRCA-2 analyses are performed.

Face-to-face encounters with counselors at a clinic are vital to ensuring that women understand the potential pros and cons of testing, and that
“Watchdog”: Activism

ACT UP and breast cancer activists at the 1995 Women and Cancer Walk.

“Nothing she’d done previously had led her to think she’d one day be an activist. Now, she can’t imagine her life any other way. ‘My anger pushed me to step out of my comfort zone,’ she says. ‘I raised my son myself since he was 4, and I’ll be damned if I leave this earth and leave him alone without kicking and screaming along the way.’”

https://www.cancertodaymag.org/Pages/Fall2018/Raising-Their-Voices.aspx
Advocate Perspective

Helping Unravel the Complexity of Cancer: The Role of the Advocate

By Carole Baas

Cancer advocates fill many positions: we counsel patients, educate the public, raise money for local and national programs, lobby for research funding, and serve on grant review panels and advisory committees. But one of our most important roles is to work with the scientific community to represent the patient’s perspective—to provide a human context for the research. It’s easy to do this when the studies are clinically-focused, it’s a bit more difficult with translational work, and it’s incredibly challenging when the research is at the basic science level. Out of PS-OC Perspectives, 2010
Research Advocates can participate in all areas of cancer research.

Cancer Research

Cancer research is a continuum, moving from Basic Research to Translational and finally to the Clinic.
NCI Definition of Research Advocacy

Research advocates bring a unique viewpoint to the cancer research process, making scientific and medical advances more timely and effective for people living with cancer... and serve as a reminder of the need for research focused on patient benefits and outcomes.

https://www.cancer.gov/about-nci/organization/oar/research-advocacy
“Research advocates play a vital role in shaping NCI’s work. They challenge us, and ensure that we never lose sight of what we are here to do – which is to improve patient outcomes by advancing cancer research. We can’t do this without the unique perspectives research advocates bring.”

~ Dr. Doug Lowy, NCI Deputy Director

https://www.cancer.gov/about-nci/organization/oar/research-advocacy
NCI’s Office of Advocacy Relations (OAR) engages cancer research advocates and serves as a link for advocate stakeholders to collaborate with NCI. OAR works with individual research advocates, local and national advocacy groups, and professional societies to ensure the collective patient perspective is included in NCI efforts to advance cancer research and improve patient outcomes.

https://www.cancer.gov/about-nci/organization/oar
Advise — Develop recommendations or advice focused on strategic directions or broad policy issues

Design — Develop new or enhance existing programs or activities

Review — Evaluate and analyze research proposals and ongoing research activities

Disseminate — Interpret and communicate scientific information for non-scientific audiences
Engaging Research Advocates

- Serve the Institute in connecting the right advocate to the right activity so he or she can provide the most effective and meaningful contributions when working with NCI.

- Connect qualified advocates to NCI activities based on need, expertise, and interest.
Advocate Involvement in Federal Agencies: NCRA

NCI Council of Research Advocates (NCRA)

- the only federal advisory committee comprised solely of advocate leaders at NCI.
- convenes around broad cancer research issues and provides the NCI Director with advice and strategic insights from the community's perspective.

https://www.cancer.gov/about-nci/organization/oar/ncra
Advocate Involvement in Federal Agencies:

Food & Drug Administration (FDA)

Patient Representatives provide FDA with the unique perspective of patients and family members affected by a serious or life-threatening disease.

Some of the ways a Patient Representative may serve are:

• On Advisory Committees, where they offer the patient perspective, ask questions, and give comments to assist the committee in making recommendations.

• As a consultant for the review divisions (doctors and scientists who review data to determine whether the medical product’s benefits outweigh the potential risks).

• As presenters at FDA meetings and workshops on disease-specific or regulatory and health policy issues.

https://www.fda.gov/forpatients/about/ucm412709.htm#Role
National Clinical Trials Network (NCTN)

“Patient advocates also participate in executive decisions in some cooperative groups in order to concentrate efforts on clinical trial results that may lead to improving patients’ lives rather than solely answering interesting scientific questions.”

Nijsten T, Bergstresser P. Patient advocacy groups: Let’s stick together. *J of Investigative Dermatology* 2010, **130**:1757-1759.
National Clinical Trials Network (NCTN)

• consists of four adult groups and one large group focused solely on childhood cancers.

• The structure also includes a Canadian Collaborating Clinical Trials Network.

https://www.cancer.gov/research/areas/clinical-trials/nctn#groups
"For the past two decades, the National Cancer Institute (NCI) has supported the involvement of patient advocates in both internal advisory activities and funded research projects to provide a patient perspective. Implementation of the inclusion of patient advocates has varied considerably, with inconsistent involvement of patient advocates in key phases of research such as concept development...
Ultimately, the benefits of more patient-centered cancer trials will be measured in the usefulness, relevance, and speed of study results to patients, caregivers, and clinicians."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6005117/
Specialized Programs of Research Excellence (SPORE)

Health Advocates in Research: A Participatory Conference

How do SPORE Patient Advocates work?

- Participate in research discussions and strategy meetings
- Ask results-oriented questions that help SPOREs focus on ways to move discoveries toward clinical applications for people
- Facilitate discussions among disparate scientific disciplines to create collaborations
- Serve on SPORE executive committees
- Help review small, "seed" grants that SPOREs can fund
- Help identify gaps and barriers in the research system, and facilitate discussions with federal agencies, national organizations, companies, and institutions to streamline the discovery-development-delivery process
- Learn why tissue is important to researchers and patients, and help researchers get what they need while respecting patients’ privacy
- Improve consent and collection processes involving human tissue
- Review surveys, instruments, consents, websites, projects, and cores
- Serve on local Institutional Review Boards
- Bring awareness of the SPORE program and its clinical trials to patient and community organizations
- Hold educational forums between patient & research communities
- Brainstorm on ways to improve the clinical trial system for participants
- Give input into clinical trial development and design
- Develop plans and tools that help explain clinical trials better

Advocate Involvement: Non-Profits

Pancreatic Action Network (PanCan)

“Together, we can know, fight and end pancreatic cancer by intensifying our efforts to heighten awareness, raise funds for comprehensive private research, and advocate for dedicated federal research to advance early diagnostics, better treatments and increase chances of survival.”

Advocate Involvement in Nonprofit Funding

Appendix A: Application Definitions of Personnel

Advocates (Optional for all grants):
Komen has a strong commitment to involving breast cancer patient advocates to provide patient perspective in the design and implementation of both research projects and Career Development Plans. Patient advocates can be involved early in the development of the project to provide input and ensure that the proposed work has impact for patients. During pre-application submission, they can assist by reviewing the scientific and patient impact section to help communicate the importance of the project to breast cancer patients. Advocates can be included on Mentoring Committees and invited to project presentations to provide the patient point of view and a different perspective to the project. They can be included in clinical trial development, providing input on potential barriers to accrual and help develop patient education materials. Advocates can also help communicate the importance of the results of the project to the public using lay language that everyone can understand. If an Advocate is involved in the proposed research project, they are required to be listed as a Key Person.
Advocate Involvement in Nonprofit Funding

II. Key Personnel:
Koren defines Key Personnel as an individual who contributes to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the Grant. Typically, these individuals devote a defined percentage of effort to the project, and have doctoral or other professional degrees. Collaborator/Consultants at the postdoctoral or graduate student level may be considered Key Personnel if their involvement meets this definition. Each Key Person must have a level of effort listed in ProposalCENTRAL (0-100%). Advocates, the Lead Mentor, and members of the Mentoring Committee may list 0% effort. Other Key Personnel must list greater than 0% effort. Salary support is not required for Key Personnel. Please note: Salary support is not allowed for the Lead Mentor or members of the Mentoring Committee. For Postdoctoral Fellowships, salary/support is allowed ONLY for the Applicant/PI.

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<thead>
<tr>
<th><strong>KEY PERSONNEL ROLE</strong></th>
<th><strong>ROLE LIMITED TO APPLICABLE GRANT MECHANISM:</strong></th>
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<tbody>
<tr>
<td></td>
<td><strong>CCR</strong></td>
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<tr>
<td>Advocate</td>
<td>Optional</td>
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<tr>
<td>Collaborator (Key)</td>
<td>Optional</td>
</tr>
<tr>
<td>Co-Mentor</td>
<td>Not allowed</td>
</tr>
<tr>
<td>Committee Member</td>
<td>Required</td>
</tr>
<tr>
<td>Co-PI</td>
<td>Not allowed</td>
</tr>
<tr>
<td>Lead Mentor</td>
<td>Required (1 per grant)</td>
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Advocate Involvement in Nonprofits

Young Survival Coalition

Research Priorities
• Metastasis
• Treatment
• Pregnancy & Fertility
• Quality of Life & Survivorship
• Risk Factors

Advocate Involvement in Nonprofits


YSC does not perform or fund clinical research. We recognize that progress on our Research Agenda can only be made through the efforts of the cancer research community, specifically scientists, researchers, practitioners, patients and other nonprofits. YSC is willing to work with and assist researchers who conduct studies that fall within our research priorities.

OUR REVIEW PROCESS AND STANDARDS

Because YSC is a nonprofit with limited resources, we cannot assist on every study or grant opportunity presented to us—so much as we would like to! To submit your request, complete the form at youngsurvival.org/researchagenda. Provide details about your study, how it fits within the YSC research priorities, and a description of the assistance you are seeking.

A YSC staff person will respond to your request within three weeks, describing our decision and availability to assist. Our decision will be based on the following considerations:

- Does the proposed research cleanly fall within the YSC research priorities and focus on young women?
- Is the study's research design and concepts sound and based on existing theory or evidence?
- Will results of research be shared with YSC?
- Timing of request — how quickly are YSC actions required and can we assist in the time needed?
- Effect level — what is being requested and does YSC have the know-how to assist?

LEVELS OF ASSISTANCE AVAILABLE

If your request is granted, YSC may be able to assist in the following ways:

- Signing an as collaborator of research submitted to granting/funding agencies, with the precise nature of YSC efforts to be decided jointly between researcher and YSC
- Provide a letter of support regarding the importance of your study and YSC’s involvement, where applicable
- Recommend and assist collaborator to assist in design, review or oversight of your study
- Share your research and study results on Facebook, Twitter, our e-newsletter and blog
- Publicize the study or trial through Facebook, Twitter, our e-newsletter and webpage to aid in participant accrual

If you have any questions, please contact us at research@youngsurvival.org
How are Advocates Trained?

Online Tutorials

Drug Development: From Bench to Bedside

Developed by Cancer Information & Support Network
WWW.CISNcancer.org
How are Advocates Trained?

Patient Education Programs
How are Advocates Trained?

In-Person Trainings

University of Alabama Cancer Center Breast Cancer Research Advocacy Training, May 2013
Examples of Advocate Involvement

University of Massachusetts Breastmilk Lab
Dr. Kathleen Arcaro
University of Massachusetts, Amherst

Kathleen Arcaro/UMass Amherst
http://www.breastmilkresearch.org/
Patient Centered Outcomes Research Institute

“Redesigning research not FOR the patient, but WITH the patient.”

~ Sue Sheridan
Director of Patient Engagement, PCORI

PCORI Think Tank: What Should PCORI Study? A Call for Topics from Patients and Stakeholders,” December 4, 2012
Should Advocates Be Compensated?

Advocate Involvement in PCORI Grant

**Consultant Costs:**

**Cancer Patients/Survivors:** $6,500 per year for each consultant for years 1-3. The consultants will consist of cancer patients/survivors, including [name redacted] and TBD. Their role is to voice their concerns and represent cancer patient and survivor priorities about the research agenda. Furthermore, they will advise the research team about suitable research processes that are respectful of and acceptable to cancer patients of reproductive age. They will help guide the vision and mission of the project.
Choosing a Research Question

What do we, as a society, think is important to research?

- Are we looking at prevention and causality as well as cure?
- Are we looking at research to benefit those who have been less empowered in the country?

Research Study Design

Designing a Research Study

• Is it scientifically valid?
• Is it sensitive to the needs of the community?
• Is it something that is going to protect those who are involved as well as those who will gain from the results of the research later?

Research Study Design

Conducting and Monitoring Research

• Who is involved?
• What are the conflicts of interest of those involved?
• How does the research team relate to the research subjects?
• Who might be there to advocate on behalf of research subjects as they navigate the process?
• Are there advocates of any kind who are present to guide the research subjects throughout the process, not just to witness the consent but to monitor safety and human subject protection, and to answer questions that arise?

Research Study Design

Disseminating Results

Are advocates getting the results of studies out to policy makers and journalists?

How might the publication process itself be biased and what can advocates do to correct that bias?

What is required to be published and how do advocates help build capacity for others to disseminate findings widely and effectively?

Rationale for PS-ON Advocate Involvement

Based on the belief that the increasing momentum for cross-disciplinary connectivity between biologists, physicists, mathematicians, chemists, biomedical engineers, and oncologists would be enriched and enhanced by vigorous and diverse public and or advocacy support, the PS-ON leadership, at program inception, incorporated the advocate voice in setting a national research agenda.

Mapping Science-Advocacy Exchange

Increasing front-end inclusion in research development and strategy
Encouraging informed bidirectional collaborative engagement
Promoting basic research and convergence
Addressing bottlenecks in cancer research

“Forwarding the imperatives — think boldly and creatively, question the status quo, and consciously break down the silos that impair collaboration — nullifies a long-held paradigm that advocates are passive recipients in convergent science settings.”
Advocacy Framework

**Infrastructure**
- Leadership
  - Shared commitment to change
  - Shared transdisciplinary team governance
  - Stakeholders as change champions
- Levers for change
  - Resources/toolkits for advocate engagement/acknowledgment
  - Logic models and systems mapping approaches to gauge performance
  - Strategies to drive advocacy input evidence base
  - Incentives for advocacy contribution (travel, honoraria, inclusion visibility, authorship) or paid staff positions

**Strategic priorities**
- Structures
  - Formalizing advocacy visibility
  - Advocacy vision aligned with research priorities
  - Establishing policies requiring transparency
  - Advocacy inclusion at study planning stages
- Skills and capacity building
  - Training to expand stakeholder knowledge and partnership capabilities
- Metrics
  - Comparative analytics assessing the value of advocacy inputs and impacts

**Practices**
- Optimizing what works
  - Bidirectional cross-continuum collaboration
  - Advocate acquisition of scientific competence
  - Advocate representation of patient preferences and program priorities
- Engagement outcomes
  - Influence research design and direction
  - Spur/catalyze innovation
  - Improve study efficiency
  - Enhance personalized impact
  - Advance advocacy equity agenda and credibility tactics
  - Share and disseminate research
  - Influence public policy

An Advocacy Program must include:

- Opportunities for Scientists to Interact with the Patient Community
- Connection with the Local Cancer Community
- Advocate Inclusion in Local and National Meetings

And address issues on how to:

- Incorporate Advocacy into the Center or Project
- Identify Interested Advocates
- Involve Advocates in a Meaningful Way
To involve advocates in research:

- Identify need for advocates
- Connect with NCI OAR
- Network with national and local cancer advocacy organizations
- Ask your institution, clinicians, researchers
- Identify Advocate Candidates
- Interview Candidates
- Integrate Advocate(s) into your project
How Do We Foster a Creative Scientific Environment?

- Build Transdisciplinary Teams
- Include Voices Outside Science
  - Patient Community
  - Artists
Advocates can:

- **Serve as a translator**, helping communicate complex ideas to other team members as well as the public.
- Provide a **different perspective** on cancer.
- Represent those whose lives have been affected by cancer and **serve as a reminder of the importance of the research**.

*Breast cancer cells* - A cluster of breast cancer cells showing visual evidence of programmed cell death (apoptosis).
"You will find, as you look back upon your life, that the moments that stand out are the moments when you have done things for others."

~ Henry Drummond: Scottish evangelist, writer and lecturer, 1851-1897