

## **Adverse Event Reports and Effect on Patient Decision Making**

Making decisions about the risks and benefits of a particular drug or treatment is difficult. The recent article in the July 3rd issue of the British Journal of Medicine, *Making decisions about benefits and harms of medicines* by Greenhalgh, Kostopoulou, and Harries, does an excellent job of covering this topic.

Announcements of product recalls and changes to labeling are published by the FDA as required by regulations. FDA offers a listserv to notify subscribers of adverse events and product recalls. For more information or to subscribe to this service go to:

<http://www.fda.gov/medwatch>, the Internet gateway to access safety information on the drugs and other medical products regulated by the U.S. Food and Drug Administration. This is an excellent way for advocates to stay up with what is happening at FDA but it may also raise some concerns especially when these recalls are publicized by the media.

FDA makes decisions about product re-labeling and product recalls based on the evidence and seriousness of the adverse events. These decisions are based on the collective body of evidence or how it would affect the population as a whole. Individual patients may feel that a particular decision was not in their best interest or they may feel that the evidence should have been collected before the product was marketed.

Greenhalgh et al cover important topic such as individual need versus population level policy, cognitive and social influences on risk decisions, and narrative influences on decision making. Because, "The balance between benefit and harm in medicine is neither simple nor static." (Greenhalgh, 2004) it is essential for advocates to understand how these decisions are made and the influencers that affect decision-making for patients.

For further reading: Trisha Greenhalgh, Olga Kostopoulou, Clare Harries "Making decisions about benefits and harms of medicines" BMJ, 2004; 329:47-50 (3July) doi:10.1136/bmj.329.7456.47 available online at <http://bmj.bmjournals.com/> (free, registration required)

## **Introducing Research Advocate Network's Advocate SkillBuilders**

As patient advocates, we are often called upon to "translate" or "interpret" results of recent research which can be a daunting task and a huge responsibility. Media coverage can also make this task more difficult because of bias and inaccuracies.

The media often influences perceptions of findings.

Research Advocacy Network feels that knowledge is the great equalizer. In or-

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*Advocate SkillBuilders (Continued from page 1)*

der to be “translators and interpreters,” advocates need tools to help them understand some of the scientific concepts involved in a research study and be able to communicate effectively with patients, researchers and other advocates. To help advocates be better equipped to face these challenges, Research Advocacy Network is introducing the Advocate SkillBuilder series. The series will be comprised of articles, links and presentations to help advocates improve their skills.

Some of the topics to be covered are:

- Absolute Risk/Relative Risk – What does it mean?
- Decision making – weighing benefits and harms of treatments
- Communicating with Researchers (in test phase)
- Collaboration and Partnerships
- How to Read a Medical Journal article
- Interpreting Scientific Presentations
- The Power of “n”
- The Drug Naming Process (existing)
- Glossaries (existing)
- Acronym listing
- Conflict of Interest – Advocacy perspective
- Statistics for the Research Advocate
- Understanding Eligibility Requirements for Clinical Trials

Look for a new SkillBuilder in each issue of Network News as well as on the website

<http://www.researchadvocacy.org>.

Ideas that you would like to see added to SkillBuilders? Let us know and we'll work on it together! RAN is here to help your efforts as an advocate be more meaningful and effective.

## 12<sup>th</sup> Annual SPORE Investigators Workshop

### Advocate Involvement in Translational Research

#### *Advocates in Action*

Since 1992, NCI's Specialized Programs of Research Excellence (SPOREs) have been instrumental in defining and leading the field of translational research.

The program's successes are the result of multidisciplinary teams of basic and applied (clinical) researchers working together to move basic research into the clinic or to determine the underlying mechanism of a clinical observation. The program has grown from four organ sites to fourteen and there are now 56 SPORE programs.

The 12<sup>th</sup> Annual SPORE meeting was held in Baltimore July 10-13. This year's conference emphasized the common themes in basic research across organ sites by presenting two Thematic Poster Sessions and Concurrent Plenary Sessions. The concurrent plenary sessions focused on Markers of Diagnosis, Early Detection and Risk Assessment, Pre-Clinical Models, Predictive and Prognostic Markers, and Therapy and Chemoprevention

While the NCI does not require advocate participation in local SPOREs, it encourages participation. This year the NCI funded a unique program to support advocates and link them to researchers. The Patient Advocate Research Team (PART) Program is lead by Deborah Collyar, a long time advocate for patient

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advocates in research. Deborah, and her PART team of Bob Collyar and Kathy Meade, arranged an extensive and helpful program for the SPORE patient advocates in attendance (the NCI paid for one advocate from each site to attend).

During pre-conference activities there was a Patient Advocate Orientation Meeting for first time attendees and a Patient Advocates' Strategic Session which addressed key SPORE issues, workshop strategies and the PART Program. Each of the three mornings began with an early bird session and offered a Q & A with SPORE investigators, a PART Program discussion, and a wrap up session. A highlight of the PART advocate program was the SPORE Patient Advocate and PI Working Lunch. This provided an opportunity for each advocate to have a one on one discussion with the primary principal investigator of their SPORE. There was also an opportunity to learn from other advocates and principal investigators about what they were doing.

An informal assessment of advocates attending this SPORE meeting was positive. It was an opportunity to hear the latest science presented, interact with researchers and advocates and become more effective advocates.

### ***Thought you would be interested.....***

- Research Advocacy Network's abstract was selected for presentation at San Antonio Breast Cancer Symposium in December
- RAN's Passport to Communication Module is currently the topic of dissertation research on knowledge transfer by PhD candidate in the University of North Texas, College of Education, Department of Technology & Cognition, Denton, Texas
- University of North Carolina, School of Public Health, Health Behavior and Health Outcomes publishes report on Health Consumer Advocacy Conference, see report at: <http://www.sph.unc.edu/hbhe/PatientAdvocacyReport.pdf>
- FDA report "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products" describing the urgent need to modernize the medical product development process and to make product development more predictable and less costly. The report is available at <http://www.fda.gov/oc/initiatives/criticalpath/>

#### **Upcoming conferences of interest:**

- **American Association of Cancer Research Frontiers in Cancer Prevention**, October 16-20th, Seattle, WA <http://www.aacr.org/2004Prevention.asp> This multidisciplinary conference will link the biology of the cancer process with its clinical prevention and reversal in preinvasive stages. It will foster translational research and strengthen the vitally important partnership between basic, clinical, and behavioral prevention researchers, and facilitate bringing new agents and therapies more rapidly to the clinic – agents that can effectively prevent or delay the development of cancers. This meeting will also provide discussion of the public policy issues important to the field of cancer prevention.
- **Cochrane Collaboration 12th Annual Colloquium** Oct. 1-3 Indianapolis, IN <http://www.colloquium.info/> Focus of the 12th Cochrane Colloquium is to bridge some of the key gaps that have been identified: gaps between The Cochrane Collaboration and clinical practice, gaps between high and low-income countries and individuals, gaps between methodologists and reviewers, and gaps between producers and users of healthcare information.
- **American Academy on Physician and Patient Research and Teaching Forum**, October 1-3, 2004, Indianapolis, Indiana "Opening Dialogues in Healthcare Communication" The Forum will provide presentations on state-of-the-art research and teaching methods in patient-provider communication. For more information visit <http://www.physicianpatient.org>

# Calendar-What is Research Advocacy Network Doing?

## September 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

## October 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

## Network News

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*Advancing Patient-Focused Research*

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### Research Advocacy Network Activities

- **September 10**—Trainers—St. Louis Affiliate Susan G. Komen Breast Cancer Foundation Research Advocate Workshop, St. Louis, MO
- **September 12**—Northwestern University Town Hall Meeting, Chicago, IL
- **September 28-30**—North Central Cancer Treatment Group
- **September 30-October 1**—Workgroup Leaders at the Summit on Clinical Trials, Washington, DC
- **October 5**—Trainer at the Pennsylvania Breast Cancer Coalition Keystone Breast Cancer Conference Scientific Training
- **October 16**—Presentation at Columbus Affiliate of The Susan G. Komen Breast Cancer Foundation
- **October 20-24**—Facilitators for Lymph Science Advocacy Program (LSAP), National Lymphedema Network Conference, Reno, NV
- **October 28-31**—Public Responsibility in Medicine Conference
- **October 28-31**—Lynn Sage Breast Cancer Conference, Chicago, IL

**Research Advocacy  
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### Features on <http://www.researchadvocacy.org>

- Advocate SkillBuilders
- Advocate Opportunities
- Fact Sheet Series: What It Means For Me
- RAN accomplishments
- Current and archived newsletters
- Survey

*Our mission: To develop a network of advocates and researchers who can influence medical research from concept to patient care through education, support and collaborations.*

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