

Promoting patient safety through peer review

by Lee Gravatt Wilke, MD, FACS; Heidi Nelson, MD, FACS; and David M. Ota, MD, FACS

In the past two issues of the *Bulletin* (*Bull Am Coll Surg*. 2009;94(12):29-30; 2010;95(1):57-58), we discussed how the American College of Surgeons Oncology Group (ACOSOG) promotes patient safety through the safe and measured introduction of new therapies, and how the ACOSOG patient advocates promote safety by having “the patient at the table.” In this article, we highlight how the ACOSOG Peer Review and Prioritization Committee (PRPC) promotes patient safety by ensuring that ACOSOG trials are well-designed, address important clinical needs and scientific questions, and are balanced for patient risks and benefits.

What is the peer review process? The National Cancer Institute (NCI) defines peer review as “Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.”** ACOSOG conducts its peer review process through the activities and actions of the PRPC,

*U.S. National Institutes of Health. Glossary of Clinical Trials Terms. Available at: <http://www.clinicaltrials.gov/ct2/info/glossary>. Accessed January 4, 2010.

led by Lee Gravatt Wilke, MD, FACS.

The PRPC is a multidisciplinary team formed to review the clinical trial concepts and protocols prior to their submission to the NCI’s Cancer Therapy Evaluation Program (CTEP). The goal of the committee is to approve high-quality, surgically relevant trials for consideration at the national level.

This administrative committee was formed in 2006, and its roster includes both academic and community surgeons and representatives from each oncologic discipline, as well as experts from each disease site. These disease site reviewers are not members of the ACOSOG disease committees, to ensure a nonconflicted review.

In the past year, surgical oncology fellows for each of the three disease sites (breast, gastrointestinal, and thoracic) have been added to the PRPC. Incorporating oncology fellows into the peer review process provides the committee with a fresh perspective, provides the fellows with an opportunity to be trained in the peer review process, and allows them to influence the future direction of cancer research.

As an administrative committee within ACOSOG, the PRPC,

over the past two years, has developed a formal charter and standard operating procedures. The typical flow of a concept would include development and approval within a disease site committee, and then submission on a standard CTEP concept (protocol) form to the PRPC. Two primary reviewers from within the PRPC would be selected to review and critique the concept. These peer reviewers would then present the concept to the entire committee during a conference call or formal on-site meeting. The PRPC is charged with making sure each clinical trial can answer three key questions:

- Is there a testable hypothesis that has adequate background data and outcomes that will improve survival and/or quality of life for the patients with this disease?
- Can the membership of ACOSOG, as a primary surgical trials group, perform this trial safely and efficiently?
- Does the trial meet one of the three primary aims of ACOSOG: neoadjuvant treatment for cancer, a novel surgical approach or technique, and/or the use of innovative molecular or imaging techniques?

Once reviewed and discussed, the PRPC decides if the concept (or protocol) should be

rejected, or accepted with major or minor revisions. A written critique with recommendations from the multidisciplinary committee is provided to the principal investigator. If the concept is accepted, revisions are performed, and then the final draft sent to CTEP for review.

In addition to its role in critical appraisal of a trial to ensure improved patient outcomes and safety, the PRPC is also charged with making sure that ACOSOG has a balanced portfolio of trials among the three disease sites. Crucial to this process is the role of the protocol developer, who works with both the PRPC and the scientific leadership of ACOSOG to ensure that competing interests are balanced financially and scientifically.

As ACOSOG has grown and increased its portfolio of clinical studies, the opportunities for tissue banking and correlative science have also grown. In response to the increased volume of bio-specimen requests, an additional review

committee has been formed within ACOSOG, the Scientific Peer Review and Prioritization Committee (SPRPC), led by Dennis Wigle, MD. The SPRPC is charged with working with the PRPC to ensure each trial has scientifically relevant correlative science studies that will advance the study of the particular disease type, and provide a foundation for future scientific research. The SPRPC is also responsible for making sure that the available tissue repository for each clinical trial is utilized appropriately to answer the most important molecular and basic science questions.

The processes, practices, and diverse membership of the SPRPC are similar to those of the PRPC. The SPRPC differs from the PRPC in that its membership includes experts with an emphasis on basic science.

If the goal of the PRPC over the last few years has been to ensure that ACOSOG pursues high-quality and clinically meaningful trials, the success of ACOSOG trials should re-

fect the success of the committee. Indeed, in this regard, the PRPC has been highly productive and highly successful. In the last two years, the PRPC has reviewed 25 clinical trial concepts, six full protocols, and five intergroup studies for endorsement. Of the six protocols that were approved by the PRPC, five have been approved by CTEP and are open to enrollment. Perhaps most impressive is the fact that 100 percent of the trials approved by PRPC, and currently open to enrollment, are accruing patients according to pre-established targets—a remarkable achievement. In the coming years, we have no doubt that these trials will impact the care of the surgical oncology patient.

Dr. Wilke is associate professor of surgery, department of breast and endocrine surgery, Duke University, Durham, NC, and is the ACOSOG Peer Review and Prioritization Committee Chair.

Dr. Nelson, of Rochester, MN, and Dr. Ota, of Durham, NC, are ACOSOG Co-Chairs.