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## ACOSOG news

# Promoting patient safety

by Heidi Nelson, MD, FACS; and David Ota, MD, FACS

When you think about the American College of Surgeons Oncology Group (ACOSOG), patient safety probably isn't the first thing that comes to mind. Your first impulse might be to associate ACOSOG with the scientific programs we support or the new techniques and therapies we are testing. In fact, patient safety is fundamental to the mission of ACOSOG. Clinical trials are all about the safe introduction of new therapies and, as a clinical trials organization, ACOSOG is squarely focused on patient safety.

We can all recall from our younger years procedures or therapies that were once considered vogue and appealing, but were later found to be ineffective or deleterious, such as sigmoid resection for constipation or hormone therapy for menopause. The goal of a clinical trials group is not only to ensure that all new and approved therapies provide more benefit than risk, but also to make sure that patients are safeguarded from inadvertent harm during the testing process. The need to safeguard patients participating in clinical trials evolved to its current state when several serious infractions became public knowledge, including the Tuskegee syphilis and the Willowbrook viral hepatitis

studies. In the Tuskegee study, patients with syphilis were left untreated long after effective therapies were available. In the Willowbrook study, state hospital residents were purposefully infected with viral hepatitis for a natural history study. This was considered an acceptable study based on the premise that all residents were at risk of developing the disease over time. To protect against similar misconduct in the future, ACOSOG has several safeguards in place, including a comprehensive review and oversight process, and the involvement of patient advocates at all critical decision-making steps.

Ensuring patient safety in clinical trials begins with the vetting of a novel idea within an ACOSOG disease committee, where a multidisciplinary team considers the potential ramifications of conducting a trial based on the proposed idea. Assuming a high degree of enthusiasm for the proposed idea, statistical input is compiled and drafted into a more formal concept, which is evaluated through a peer review process. The ACOSOG Peer Review and Prioritization Committee is a non-conflicted multidisciplinary team of experts that provides due diligence on the merits and feasibility of the proposed

study, and decides whether it is appropriate to expose patients and the group to the risk that may come from testing the new therapy. As ACOSOG is a government-sponsored clinical trials program, the National Cancer Institute (NCI) also reviews and issues approval on the concept, based on the strength of its scientific foundation and potential benefits of the study without undue risk to patients. Once the trial is NCI-approved, it moves on to either a national or local institutional review board and undergoes one last non-conflicted review before it can be opened for patients to participate. Once a trial is opened, emphasis shifts away from the trial idea and on to the experience of the patients and the institutions conducting the trial.

Patient adverse events in the course of a trial are monitored in a graded fashion, with specific reporting guidelines based on the seriousness of the event. Patient adverse events are followed on a routine basis (as part of the ACOSOG Data Monitoring Committee reports, for example) and they are also followed in a rapid response manner when a certain severity or frequency of events triggers pre-specified rules for halting the trial at an early stage.

To ensure that patient safety

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is a priority at the institutional level, each participating institution is periodically reviewed by an ACOSOG audit team. Field auditors review local records to make sure the institution is compliant with federal regulations. This audit information, along with other information on the timeliness and cleanliness of trial data, is reviewed by the ACOSOG Audit and Membership Committee for oversight and action where appropriate. Data integrity and federal regulatory compliance provide key metrics for ensur-

ing that there are no breaches in the good-faith participation of investigators and patients in this process of scientific inquiry. To complement this complex oversight process, ACOSOG has enlisted a team of patient advocates.

Patient advocates have been integrated into all levels of decision making within ACOSOG, including the Executive Committee. Patient advocates, although relatively new to the NCI Cooperative Group over the last decade, are growing in their numbers and expertise. In

a short span they have become familiar with the complexities of the diseases, the treatments, and the conduct of clinical trials. In a future issue of the *Bulletin*, we will introduce Bettye Green, RN, and her team of advocates to learn how they contribute to the success of the ACOSOG enterprise and how they provide a unique strategy for safeguarding patient safety in cancer trials.

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