Institutional Review Boards and Safety Interventions

What is so bad about being so good? That about sums up the reaction of some oncologists to news that consent forms should have been used in a study demonstrating that checklists dramatically lowered bloodstream infections for catheterized patients. The investigation¹ of 103 intensive care units in mostly Michigan hospitals showed reductions throughout the 18-month study period. But the findings became an unexpected source of controversy when the Office for Human Research Protections determined there had been inadequate use of hospital institutional review boards (IRBs) and that patient consent was necessary—a position from which US health officials now seem to be retreating.²

Peter Pronovost, MD

Nonetheless, “there has been a huge chilling effect from this,” said Peter Pronovost, MD, the lead investigator of the study and a professor of critical care medicine at the Johns Hopkins School of Medicine. And it is a chill that has been shaking up cancer care.

When the Institute of Medicine issued a report nearly 9 years ago suggesting that many cancer patients were not receiving state-of-the-art care, ASCO initiated the National Initiative on Cancer Care Quality.³ That move was lauded by the scientific community. However, some researchers correctly predicted that such efforts might mean stormy weather ahead, as oncology grappled with ways to implement safety goals.⁴ Meanwhile, Congress increasingly began linking measures of quality control with reimbursement.⁵

Perhaps that is why oncologists may have been ahead of the curve, apparently avoiding the risk of reprimand that Pronovost and colleagues encountered. Those error-cutting checklists, along with IRBs, have been in fairly common use in cancer care—even in places that once might have seemed surprising outposts for advancement, like the panhandle of Texas and the plains of Iowa.

“IRBs can be difficult to do in a practice setting,” acknowledges Martin Wiesenfeld, MD, a medical oncologist and the principal investigator of the Cedar Rapids Oncology Project in Iowa, an award-winning group with ongoing clinical trials. A lot of guidance can be found online at the Office for Human Research Protections Web site of the US Department of Health and Human Services, he says. From consent form instructions to ethics committee recommendations, the office provides information that is a virtual template, helpful to community-based researchers.

Not that he and his colleagues found it easy to form an IRB back when they needed one. The Cedar Rapids Oncology Project began its research more than 15 years ago, as part the National Cancer Institute Community Clinical Oncology Program. “It was a lot of work and effort to get to this point,” Wiesenfeld says. However, he adds, it was not complicated—just time-consuming. There are two participating hospitals, so the IRB is a joint one between the pair—a fairly unusual structure, he concedes, but one that makes sure “everyone’s in the loop.”

Seah Lim, MD, PhD

Seah Lim, MD, PhD, who heads the Texas Oncology Cancer Center in Amarillo TX, is also a longtime advocate of monitoring and quality assurance in a medically valid way. In fact, he thinks it is essential, even in a small community setting, and especially if patients are treated outside standard protocols or are being treated with a new approach. Lim directs the only stem-cell transplantation program in a 500-mile radius, and he also

has a laboratory research program funded by the National Cancer Institute.

“We routinely use a checklist for the administration of chemotherapy, which includes two levels of safety checks,” he explains. The first check occurs after the prescription of the chemotherapy, when the in-house pharmacists make sure the doses of the chemotherapy are correct and that there are no potential interactions with other medications. The second check is performed by two nurses just before chemotherapy is given, to ensure that it is administered to the right patient and also at accurate doses, he notes.

“In my experience, it is only through the formal analysis and peer review of the data that one can be absolutely certain how well or badly we fare in treating our patients, when compared to tertiary care centers,” he says.

He relies heavily on his colleagues at Texas Oncology, a large statewide independent oncology practice, where physicians regularly evaluate his data and send it for peer review and publication. Texas Oncology, which is part of US Oncology, has a quality oversight committee that reviews all pharmacy activity throughout the network on a quarterly basis. All occurrences are reported through a Web-based reporting system for review by both the local site and the quality committee. A number of medication safety recommendations have come through this mechanism, he observes.

So when is an IRB usually required? When research is funded in part by federal grants or involves the use of a US Food and Drug Administration–regulated product, according to David Forster, JD, vice president of compliance at the Western Institutional Review Board in Olympia WA. And, he cautions, even if the research lacks either of those characteristics, an IRB still can be required.

it,” even if no other criteria apply, he adds. In fact, IRB exemptions for any medical research, particularly approaches that could constitute clinical investigation, are fairly narrow. However, they can be found in easy-to-access government guidelines.⁶

For any physician in a community-based practice who wants to conduct original research but who has no academic affiliation, partnering with an IRB at a local hospital or medical center is one possibility, he advises. Another option is to contact an independent IRB, such as Western’s, and simply ask someone like Forster, “do I need an IRB for the following plan?” Many such institutions will provide free counseling initially, though he points out that a fee is often charged for a formal, written determination.

Any time an investigator uses comparison and control groups, it is wise to have an IRB, he stresses. Some local and state regulations call for such review—and so do many journals. “So, if you are going to submit for publication, you may need

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