‘Brave’ new book—AP quality management for everyone

Anne Ford

January 2017—What does it take to produce and edit the first book on AP quality management that the CAP has published in more than a decade? A diverse network of experts, a commitment to comprehensive quality assurance, and, says co-editor Qihui “Jim” Zhai, MD, a bit of bravery.

Dr. Zhai

“We all talk about professional mistakes, but we don’t want to talk about them in public,” Dr. Zhai says. He’s referring not to any misstep of his own but rather to the chapter he contributed, which lays out a recommended method for handling cases in which an anatomic pathologist has made a mistake leading to a significant adverse event. “I haven’t seen elsewhere this discussion of how to respond in order to minimize damage for the patient once a serious mistake has been made,” he adds. “It took some courage to put this in writing.” Dr. Zhai is a professor and consultant pathologist and medical director of the FISH laboratory in the Department of Laboratory Medicine and Pathology at Mayo Clinic, Jacksonville, Fla.

That damage control discussion is, of course, just one component of *Quality Management in Anatomic Pathology*, which covers approaches to quality management—approaches contributed by experts from academic medical centers, community hospitals, and “everybody in between,” says co-editor Gene P. Siegal, MD, PhD. Dr. Siegal is the RW Mowry endowed professor of pathology at the University of Alabama at Birmingham School of Medicine (UAB) and executive vice-chair of pathology, UAB Medicine. “We’ve been very sensitive about representing the diversity of our profession and our country,” he says.

The volume, released in January, comprises not only chapters on general topics such as regulatory compliance and quality management plan design but also specific chapters on QM in histology, intraoperative consultation, cytopathology, autopsy, immunohistochemistry, and molecular diagnostics, as well as discussions of informatics (see story, page 57), ISO 15189, and specimen tracking systems.

Though meant to function as a primer rather than an encyclopedia, the book is quite comprehensive, Dr. Siegal says: “I think the chapter on how you design a management plan for your institution is really terrific. It lays out how to begin if you’re starting at zero.” Its authors are Aleodor Andea, MD, MBA; Jeffrey Myers, MD; and Scott Owens, MD. “And at the other end, Dr. [Richard] Horowitz wrote a wonderfully all-encompassing chapter [“Laboratory quality management from afar”] based on the experience of a lifetime in practice, both in community practice and in academia. Here’s a person looking back on 50-plus years in the business. You can’t get that from a young person who just finished their fellowship.”

Sound intimidating? Dr. Siegal promises it isn’t. “The book is purposely made to be easy to read. You do not have to be a Talmudic scholar to get through this,” he says. “There are some chapters that are relatively short, so in a couple of minutes, over a sandwich, you can read them.”

The volume is designed to function as a resource for “almost everybody who is involved with anatomic pathology,

from the pathologists to the medical technologists who are preparing the slides," Dr. Zhai says. "The idea is to establish a culture that should be burned into everybody's neurons, everybody's blood." It's also designed for readers at every stage of their career. "Quality assurance has nothing to do with how many years you have been practicing," he points out.

For that matter, its editors say, the volume can be used as a supplemental text for residents and fellows as well. "We're hypersensitive to the need to educate the next generation of pathologists. So we have tried to write this in a way such that you don't have to come to it with a deep knowledge of what's happened before," Dr. Siegal says.

Readers will find a chapter on legal and regulatory issues surrounding telepathology and molecular pathology, written by pathologist and lawyer Timothy Craig Allen, MD, JD. "This is an emerging area right now, and there's a lot of angst about it," Dr. Siegal says. "In the old days, if you had a challenging case, you'd send it to your favorite expert and they'd render an opinion, and that would be the end of it. Now telepathology raises a whole bunch of issues. Many states have said: 'Wait a minute. Why is Dr. Siegal sitting in Alabama making a diagnosis for a patient in California? Is he licensed in California?' All the answers aren't in yet."

Dr. Siegal

Laboratories that are struggling with identifying and remedying common CAP accreditation deficiencies in anatomic pathology will find the book useful in this regard, Dr. Zhai says: "It's closely integrated with CAP inspection; it's very practical."

For example, the chapter on quality management in histology discusses one of the most commonly cited deficiencies, ANP.22983—which requires laboratories that process breast specimens for prognostic testing to have procedures and protocols in place to monitor and document both cold ischemic and total fixation time—and provides concrete suggestions for remediation, such as monitoring total fixation and cold ischemic times on all tissue specimens. And the immunohistochemistry chapter's discussion of the need to include a positive control for each antibody directly pertains to ANP.21460, "Validated tissue controls are required for each special stain."

Throughout the book, the authors have done their best to incorporate examples from their own laboratories. For example, Zongming Eric Chen, MD, PhD, director of immunohistochemistry at Geisinger Medical Laboratories, Danville, Pa., and his co-author Fan Lin, MD, PhD, Geisinger's director of anatomic pathology, include in their chapter on immunohistochemistry a description of how their institution implemented a system that allows every IHC stain to be reviewed for quality control purposes.

"You want to have a system that at least makes sure that from test to test, the result will be reproducible," Dr. Chen says. "So with that in mind, standardization is the key. Even before the staining process starts, standardize as much as possible the protocols used for tissue fixation, processing, and slide preparation throughout all specimen types, including cell blocks from cytological specimens."

"As an important indicator of the global quality of the staining process, external controls mounted on each slide separate from the testing patient tissue are very useful for quality control of each individual stain," he says. His laboratory uses a set of highly selected control tissues, puts them into a standardized format (tissue microarray), and matches them with corresponding antibodies. "They provide a unique combination of staining pattern for each individual antibody, usually with strong and weak positivity in some tissue while negative staining in others," Dr. Chen says. "And this pattern should be reproduced on every single slide for the specific antibody in every single

run." The setup of these control sets was from small punches of circular tissue made from larger normal or tumor specimens. Recently, however, the Geisinger laboratory has been experimenting with cell blocks made from a mixture of highly selected cultured cell lines for better standardization.

"Designated technologists with experience in IHC are taught to recognize these different staining patterns for different antibodies," he says, "and they do quality control for each slide as they come off from the staining machines. Only the ones that pass this test will be sent to a pathologist for review. Any slides that failed the test will be reviewed by a pathologist lab director to determine appropriateness of the stain and for potential technical troubleshooting."

Scattered throughout the book are sample forms—such as a requisition form monitor, a frozen section turnaround time report, and an intraoperative consultation QA review disagreement worksheet—that readers can copy, modify as needed, and use in their own laboratories. Their purpose? "To help people not reinvent the wheel," Dr. Siegal says. "These are templates that people can build on for their own programs. We wanted to make these painless for people who are very busy and who have a huge obligation to cross all the t's and dot all the i's."

The notion of supplying these templates, he adds, arose in part from his frequent encounters of outdated or inadequate forms while performing Laboratory Accreditation Program inspections. "It's only when the inspector is there and the laboratory gets cited for something that's not appropriate or not state-of-the-art that people realize, 'Oh, I didn't know you couldn't use this. It worked for me in 1973.' Well," he says, "it's 2017."
[hr]

Anne Ford is a writer in Evanston, Ill. To order Quality Management in Anatomic Pathology (PUB125), call 800-323-4040 option 1 or go to www.cap.org, Shop tab. CAP member price: $92; for others: $115. To purchase an ebook ($81), go to ebooks.cap.org.