In vivo microscopy checklist ready when labs are

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September 2015—Why issue accreditation requirements for a technology before it's seen widespread adoption? For the same reason you close the barn door before the horse has wandered out.

At least that's the view of Maria M. Shevchuk, MD, who, as chair of the CAP's In Vivo Microscopy Committee, helped develop the new in vivo microscopy section of the Laboratory Accreditation Program's 2015 anatomic pathology checklist.



Dr. Shevchuk

"We want to be ahead of the game," says Dr. Shevchuk, who is associate professor of pathology and laboratory medicine at Weill Cornell Medical College and associate attending pathologist at New York Presbyterian Hospital. "We want to do everything possible to foster IVM, so that if any laboratory wants to do it, the checklist will be there for them."

Further, says committee member Sharad C. Mathur, MD, "in some instances IVM technology has been initiated through a clinical department, and pathologists have been called in for consultation and interpretation without a good structure for how this program is to be administered. This document gives the pathology community some of the things it needs to provide high-quality care using IVM." Dr. Mathur is chief of pathology and the laboratory medicine service at the VA Medical Center, Kansas City, Mo.

IVM allows two- and three-dimensional microscopic images to be obtained in real time from living patients. It can be used to obtain targeted biopsies, screen organs for occult microscopic disease, and make microscopic diagnoses when tissue cannot be excised. Confocal microscopy, optical coherence tomography, multiphoton microscopy, and optical spectroscopy and spectroscopic imaging are all IVM technologies.

"There are multiple organ systems or clinical situations in which IVM has shown promise," Dr. Mathur says. "The areas in which it has emerged include gastroenterology with endoscopy, dermatology, and some cardiac imaging applications. But it is expected that other applications will increase. The technology has been around for probably a decade or more, but its clinical applications and especially its clinical utilization have really taken off over the last five years or so."

As for the checklist requirements, "they're the same as we would create for anything else in anatomic pathology, but transferred to this field," Dr. Shevchuk says. For example, ANP.57150 says, "IVM services are included in the laboratory's or institution's quality management plan," while ANP.57300 says, "There are training records for all users of the IVM system."

Says Dr. Mathur: "The IVM checklist was designed primarily to address items such as patient identification, IVM data set identification, development of quality plans, and validation of systems, as well as user training. It also addresses items such as appropriate use and content and structure of reports."

He expects at least one of the requirements, ANP.57250, to draw questions. "The one that might generate the

most comment has to do with system validation and appropriate use," he says, "because there are some commercially available IVM systems, but there are also many homegrown systems, so there is only a limited amount of standardization. Therefore, validation is something every institution will have to perform with its own clinical utility in mind. The explanatory note that accompanies this item does specify that this has to be individualized for each laboratory and be under the guidance of the director of the service. Then it provides some general guiding principles about how to achieve this."

The IVM committee was careful to write the IVM requirements in such a way as to be usable by non-pathologists, Dr. Shevchuk says. "Should gastroenterologists want to use it when they do IVM, to make sure their quality is there, they can do that," she says. "In other words, we've made the quality measures applicable to any use of IVM. The thing that's special is that we spoke with several gastroenterologists, and they said, 'This is fabulous,' because there are groups of them doing IVM, but they by no means have these quality measures and guidelines. They would like to emulate us."

Over the next year or so, the IVM committee will consider creating a more specific checklist that will address ex vivo applications of IVM, in which IVM technologies are used on specimens that have been removed from a patient. That's because, Dr. Mathur says, IVM adoption in pathology departments may pick up as more applications for ex vivo use of IVM become well known. "It is likely that pathology departments will find applications of IVM in real-time assessment of specimens. This may serve as an adjunct to the types of rapid assessments we currently do, such as frozen sections. It can also be potentially used for tissue selection for ancillary studies or biorepository banking."

Dr. Mathur points readers to the CAP's In Vivo Microscopy Resource Guide, which the IVM committee updates annually. "It is an absolutely phenomenal resource that summarizes the latest applications and literature associated with IVM and its various applications," he says. "It also contains introductory sections that go over basic definitions of what IVM is, what the technologies are and how they're used, and details on applications in various organ systems, and it has sections devoted to validation and standardization of IVM as well as a listing of all the other CAP IVM resources that are available." In it, too, are interviews and discussions with early IVM adopters.

In Dr. Shevchuk's view, it's important for pathologists to become acquainted with this technology. "In some cases," she says, "it may be the best way to do what we're doing. For example, in the selection of tissue for genetic/molecular studies, IVM may become the standard of care for what we are already doing in the lab. We would not have to consume tissue to identify the 'tumor-rich or diagnostic areas' to be sent for testing. And there would be a permanent digital record of the tissue to be tested."

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Anne Ford is a writer in Evanston, III. For the IVM Resource Guide, go to <u>www.cap.org</u> and click on Resources and Publications.