Visuals to the fore in new histology labeling guideline

Anne Paxton

June 2015—Like laboratorians, filmmakers split their workflow into three phases. In film, they are pre-production, production, and post-production. When flubs occur on a movie set, "We'll fix it in post," often said sardonically, is the fallback game plan to keep things on schedule and use visual and sound effects to cover up mistakes.

But you'll never hear "We'll fix it in post" in a laboratory, where errors have to be stemmed in the preanalytical phase, if not before. The mantra has to be "We'll fix it in 'pre.'" And that's exactly the purpose of the new guideline that the College's Pathology and Laboratory Quality Center and the National Society for Histotechnology have developed for accurate and consistent labeling of blocks and slides in surgical pathology (Brown R, et al. *Arch Pathol Lab Med.* Epub ahead of print April 21, 2015. doi:10.5858/arpa.2014-0340-SA).

Dr. Brown

In a quest to increase accuracy of patient identification and make labeling more standardized, the CAP and the NSH jointly convened an expert panel to produce the guideline. The panel's main conclusion: Two human-readable, visual checks are needed. Titled "Uniform Labeling of Blocks and Slides in Surgical Pathology," the guideline has as its major recommendation that histology laboratories use two unambiguous patient identifiers, one of which includes the accession number and case type, on tissue samples and the products made in the histology lab, including all tissue blocks and microscopic slides.

For decades, the accession number has typically been the only identifier on all histology materials, says Richard W. Brown, MD, CAP co-chair of the panel. With this guideline, "We're basically saying to use the lab-assigned accession number and then a second data point—the patient's name or a medical record number or something else." Added expert consensus opinions in the guideline address the order and format in which identifying elements should appear.
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Key components of CAP/NSH labeling guideline for blocks and slides

- All blocks and slides should be unambiguously labeled using two patient identifiers.
- When an accession number has not yet been assigned, blocks and slides should have at least two patient identifiers, one of which is the patient name.
- Blocks obtained from a single specimen should be labeled sequentially.
- Multiple slides obtained from a single block should be labeled sequentially

in order of cutting.
- The histochemical, immunohistochemical, and/or special procedure code should follow the accession, specimen, block, and slide identifiers on each slide.
- On paraffin blocks, the accession number should be the most prominent printed element (in large print or bolded), followed by the patient name or other second identifier.
- No recommendation is made regarding standardization of abbreviations and conventions.

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The two-identifier concept has for many years been a patient safety goal of the Joint Commission, as well as of the CAP through the Laboratory Accreditation Program's laboratory general, anatomic pathology, and cytopathology checklist requirements. "It's well established in the literature that when you add a second data point, it lends a higher level of assurance that you have an identification correct," says Vincent Della Speranza, MS, HTL(ASCP), NSH co-chair of the joint panel. By issuing this new guideline, the CAP and the NSH are advocating for two identifiers in anatomic pathology.

The complete list of guidelines contains two recommendations relating to the double identifier and 10 expert consensus opinions, which are ordered from the most general to the most specific. Dr. Brown, who is medical director of System Laboratory Services at Memorial Hermann Health System in Houston, explains why only the two strongest guidelines, which address the double identification, are at the "recommendation" level, while others are at the level of "expert consensus opinion."

"A recommendation has some sort of evidence behind it, while a consensus opinion is based on the experience and expertise of the panel. The first and fourth guideline statements—which really express the same priority, the need for two human-readable identifiers—were elevated to recommendation level based on the fact that the College, the Clinical and Laboratory Standards Institute, and the Centers for Medicare and Medicaid Services all say you should use two identifiers."

The panel considered six key questions, and the 12 guideline statements address them one by one, Dr. Brown says. "They also follow processes as you go through the lab, so we start with how one should create an accession designation, then what we recommend as the essential elements for labeling of blocks, labeling of microscopic slides, and the order we think is best. For example, the accession designation on microscopic slides should be the primary thing one sees, whether in the biggest font or in bold, and then the secondary identifier."

Other guideline statements include calls for: labeling each block obtained from a single specimen sequentially with a unique alphanumeric designation that can be unambiguously linked to a gross description with the pathology report; labeling multiple slides cut from a single block sequentially in order of cutting; and labeling each slide's procedure (FS for frozen section, TP for touch preparation, AFB for acid-fast bacteria) after the accession, specimen, block, and slide identifiers.

One area, standardization of abbreviations and conventions, was designated "No recommendation." The expert panel considered whether to require a standardized abbreviation for the names of all the stains done in histology, and at one stage a full list of abbreviations was proposed. But a recommendation wasn't practical, Dr. Brown says.

"First, there are no guidelines for what those abbreviations should be and people might not agree with our choices. Second, somebody has to be in charge of maintaining those abbreviations as new stains are developed. So we said no. It would be ideal if everybody used the same three-letter abbreviation for a particular stain, but it's not

something we see as possible at this time." However, the guideline is slated to be reviewed every four years, or earlier if needed, and revised when the expert panel so recommends.

Della Speranza

Histology labs have not necessarily been behind other disciplines in modernizing their labeling, says Della Speranza, a former president of the NSH. It's more that they didn't think there was a need to standardize. For example, there have been few instances in which histology labeling was found to be an issue in malpractice cases. In conducting research for the guideline, "We didn't find significant reported data that suggests the labeling or a lack of standardization of labeling has created problems in medical laboratories. That would make it a lot easier to get people to buy in that something needs to change."

At a recent presentation to members of the NSH, he asked 150 people in the audience if they knew how to label blocks and slides, and they answered yes. "Each of us, even though we work in our own individual settings, believes we know how to do this properly. But now that idea is being challenged. And I think the guideline is really the beginning of getting people to understand the value of standardization," says Della Speranza, manager for anatomic pathology services at Medical University of South Carolina.

The guideline project was initiated after one pathologist, who was doing a great deal of consulting internationally, contacted the College with concerns, Della Speranza says. "This was a renowned expert in cancer pathology, so he has the opportunity to receive slides from all over the world. And he very eloquently pointed out how difficult it can be when going through a case that's been referred to him by some other facility. People use different approaches to labeling their cases, and the consultant pathologist could very well make an error inadvertently simply because someone used an unorthodox means of labeling."
That expert prompted the College to take the lead on producing standardized guidelines to facilitate interpretation from institution to institution, Dr. Brown says. "Any time one gets outside of one's lab, you lose the internal knowledge. Everyone knows how their own blocks and slides are labeled because they deal with them every day, but going outside these institutions, that's a different story."

The use of consultation follows a trend, over the past two decades, of more second opinions in general being requested in all areas of medicine, but certainly in pathology—and particularly in cancer cases, Dr. Brown adds. Says Della Speranza: "We're dealing with a much more sophisticated population of patients now. They have Internet resources and other tools to educate themselves, but they are going to be much more proactive. So that's leading to an increase in these consultative additional diagnoses."

Unfortunately, the new guideline's recommendations for two identifiers on each label in surgical pathology has also generated the most misunderstanding and controversy, Dr. Brown says. "There was concern about whether a barcode could constitute a second identifier. Yes, it can. But our strong belief was that there should be two human-readable identifiers on both the blocks and slides. It increases your reliability to have two visual checks, and I think most pathologists understand that. Having not just a number like '15-431' but also something else you could match up is important." Typically it's the patient name that provides a strong second check. "Visually, it will prompt you to say, 'Wait a minute, that's not the same name,'" whereas two numbers like 431 versus 437 might look too similar for a discrepancy to be noticed.

Everyone on the panel, which was selected based on specific expertise in histology practice, believed strongly that

names or initials are the right way to go. It's a belief based on experience, Dr. Brown says, "because we've all seen examples where two numbers were transposed and things got mixed up."

Specimen handling in the traditional clinical histology laboratory is complex. With the multiple handoffs that occur in accessioning, dissecting, moving to cassettes, loading onto the processor, preparing paraffin blocks, cutting slides, matching the slide to the original requisition, and then sending the slide to a pathologist to read, Dr. Brown says, opportunities for error abound. In addition, in many parts of the country, a core histology lab processes tissue for multiple hospitals, then sends the slides back. "So that adds another level of complexity."

Some 15 years ago, when pathologist David B. Troxel, MD, collected evidence from The Doctors Company, the largest private malpractice insurer for pathologists, "he found a subset of malpractice cases in which the cause of the error that led to patient harm was in fact some misinterpretation of what slide or block went with what patient's tissue," Dr. Brown says (*Am J Surg Pathol.* 2004;28[8]:1092–1095). "So there are multiple chances to mix something up between patients. That was really the first time there was a general 'call to attention' that histology lab processes had a role to play." More recently, a CAP Q-Probes study found a labeling error rate of 1.1 per 1,000 cases (Nakhleh RE, et al. *Arch Pathol Lab Med.* 2011;135[8]:969–974).

In most labs, errors of this sort are uncommon, Dr. Brown notes. "So you're at a very low number to begin with. But you certainly have the opportunity to put in place safer processes by standardizing the blocks and slides. That was the central objective we had."

Still, the CAP/NSH panel that worked on the labeling standard was surprised at the dearth of evidence. The group's research found no published studies in which a specific non-barcoded label content was demonstrated to reduce errors in identification, and indeed most studies on histology quality practices do not specifically reference labeling content at all. "In our review, we were surprised to see there weren't very many studies that were applicable to what we were doing. This was meant to be an evidence-based guideline, but in fact there was no evidence," Dr. Brown says.

Barcoding may be a cost-effective means of dealing with the complexity of the histology laboratory, depending on how you define "cost- effective," Dr. Brown believes. "Barcoding is certainly the best way to ensure patient safety in terms of labeling practices." But how the recommendations and other guideline statements will mesh with barcoding in the AP laboratory is an open question. Says Della Speranza, "We don't actually know how many AP labs have barcoding right now, but anecdotally, among the expert panel members who have a lot of experience in histology, the majority of hospital labs in the U.S. do not have anatomic pathology barcoding at this time." At MUSC, "we've adopted interfaces between the LIS and HIS and the equipment that labels blocks and slides, but they don't talk to each other in some cases. And of course, barcoding is very costly, particularly so in AP because of all the steps in the process."

Della Speranza brought barcoding into the MUSC laboratory six years ago. He found it can be useful for overcoming the fatigue that humans suffer from repetitive work. "Our ability to read numbers accurately tends to diminish over time from that fatigue," he notes. In some cases, the machines are going to be less fallible, but in some cases the barcodes aren't readable for various reasons. Moreover, he notes, the barcode is a symbolic representation that humans cannot interpret and will disregard, which creates different issues. "I have learned firsthand all the things that can go wrong with barcodes. We have a tendency to think barcodes are going to prevent errors, but they actually don't. They just create a different type of error." One important shortcoming is that a barcode read in his laboratory, Della Speranza says, may not be readable in another institution using different software.

However, the point of the CAP/NSH guideline was not to accelerate adoption of barcoding, but to optimize human-readable labels. That was another one of the controversies, Dr. Brown says. "People thought we were trying to suggest that barcoding is not a good idea in AP and we should go to handwritten or human-readable identifiers instead. But that was certainly not the intent. What we're saying is there are many, many labs that don't have barcoding technology and probably won't in the foreseeable future. So we need to make sure that for those labs still using human-readable identifiers—and many labs still handwrite their blocks and slides—we make those labels

as error-proof as possible."

One of the major concerns of those who commented when the guideline was proposed was privacy. Dr. Brown thinks some of the concern may have stemmed from a misunderstanding of the guideline's core recommendations. "You certainly don't have to use the entire patient name. We didn't mandate that at all. We just suggested that's one thing you could use. There are many possible second identifiers, and name is just one that people think of. You could use two initials or the first three letters of the last name or any number of possibilities."

Even so, the HIPAA privacy rule does not bar display of a patient name, he says. "You just have to keep it confidential. So if one does have a name on blocks and slides, they need to be in secure areas, not lying about where anyone can see them. And that was a point we made in the article." That there is not enough "real estate" on a paraffin block to write the whole name also should not be an issue, because the whole name is not required. "Again, initials or first letters would work—you just need that visual cue." Of course, Dr. Brown notes, when one handwrites two things, that doubles the chances of error, but having two things to match against each other results in a stronger check against error that, on balance, outweighs the possibility of making an error on that second identifier.

Privacy could be an issue in labs that may not have files in a secured room that can be accessed only by authorized personnel, Della Speranza notes. And discard would be important. "The College requires that slides or blocks be kept for a minimum of 10 years, so when it comes time to discard those, if there is a label with a name, I think some care would have to be taken to avoid placing the identity of that person at risk."

Aside from such concerns, he sees the new guideline as a necessary adaptation to changing practices in AP consultation. "It's common for laboratories to sometimes forget that a system that works in your lab may or may not be understandable to someone outside your lab," Della Speranza says. "So standardization can only benefit everyone, whether it's a facility that receives cases and consultations or a smaller facility that's sending its case out because the patient is going to be treated elsewhere."

In developing the guideline, the panel was not trying to be proscriptive, Dr. Brown emphasizes. Fundamentally, the histology labeling guideline is still a guideline and should be applied as it best works within each individual lab, he says.

"We aren't telling people how their blocks and slides have to be labeled down to the last piece of information. There are many different ways to get to a second identifier. We're merely pointing out what we regard as the essential elements and how they should be ordered. Ultimately, we are trying to make recommendations for the most practical solutions that will provide the greatest patient safety."
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