Personalized Medicine?

Who Has the Tissue?

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This issue of *Archives of Pathology & Laboratory Medicine* includes a white paper commissioned by the College of American Pathologists (Dash RC, et al) that describes the many elements that need to be recognized and addressed in the acquisition of biospecimens and their storage in biorepositories. The document is directed to community pathologists and highlights some of the benefits and opportunities for community-based anatomic pathology laboratories in establishing research-quality biorepositories. To be sure, appropriate and uniform specimen selection, fixation, and storage along with detailed, retrievable documentation are critical to the use of any such biospecimens for future inquiry. Pathologists have a long-standing tradition of maintaining surgical pathology archives of tissue and making them available to support these research efforts, usually out of a sense of professional responsibility if not direct research interest. These motivations have been as true for the community pathologist as for the academic, and there is little argument that the biospecimens for future research will need to come from the community as well as from the university medical centers. But establishing and maintaining a high quality biorepository demands investments of time, resources, and money. The white paper describes several scenarios in which laboratories can develop revenue-producing (or at least self-supporting) biorepositories to support these critical research efforts.

There is a much more practical message embedded in this paper that is critical for all pathologists wherever they practice. As the acknowledged curators of vast archives of microscope slides, paraffin blocks, and cytology smears, pathologists already have responsibility for these clinical biorepositories. The importance of maintaining these stores has become increasingly evident in the past year with the introduction of targeted therapies for colorectal cancer, lung cancer, and malignant melanoma, each dependent on the analysis of specific bioanalytes (KRAS, EGFR and ALK, and BRAF, respectively). In our modest molecular diagnostics laboratory in the past 3 months, more than 20% of requests for testing of those analytes were for specimens acquired prior to 2011, and not infrequently as early as 2006 and 2007. In part, this is a consequence of novel drugs first receiving approval as third-line therapies. Consequently, the use of these drugs is not considered until sometime after initial diagnosis, after first- and second-line therapies have been tried. It is only after establishment in this setting that these drugs are evaluated for earlier use. It is reasonable to think that this pattern of new drug introduction will continue, and the need to maintain access to stored slides and blocks for future molecular evaluation for patient care will be critical.

See also p 668.

In addition to access, all of the details reviewed in the white paper regarding specimen collection, fixation conditions, storage conditions, etc, will apply. My own experience in multiple institutions is that most laboratories are not prepared for this. Too often my requests for retrieval of archived materials are met with apologies for missing blocks and lost slides, not infrequently prompting a hurried search by histology personnel into pathologists' offices and cardboard boxes of blocks that have been awaiting refilling for months. I don't think this is an uncommon experience. Pathologists in all settings should question whether their current storage, tracking, and retrieval capabilities will stand up to the kind of scrutiny that this kind of surgical pathology practice will demand.

This is the key message here: we are evolving into a new kind of surgical pathology practice, with a subtle but very real transformation in what it means to be a pathologist. Given the capabilities of new technologies and our understanding of molecular pathology, our responsibility to our patients does not end with our evaluation of the microscope slide and the issuance of a diagnostic report. We truly are the caretakers of each patient's tissue thereafter. The maintenance of a high-quality biorepository of patient specimens is not an option that a pathologist, community or academic, can choose to ignore. Likewise, as the white paper points out, this is a clinical activity that pathology departments need to budget for, and that institutions need to support with space, personnel, and information technology capability. As a professional activity of pathologists, clinical biorepository maintenance needs to be acknowledged, and pathologists should be compensated for their effort.

As pathologists we know that if the advances of molecular medicine are to be realized by individual patients, the tissue specimen is critical. This is our opportunity to bring ''personalized medicine'' to our patients, in whatever setting we practice.

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