MEDICAL-LEGAL CONNECTION

PART II. THE EVOLVING STANDARD OF CARE AND THE ROLE OF NEW TECHNOLOGIES IN RISK REDUCTION

Mark S. Sidoti, Esq

A discussion of the standard of care applicable to cervical cytology screening, and the ways in which use of the new technologies can reduce liability risk for laboratorians and their clinicians clients.

This article is the second in a two part series. Part I, entitled "Liability Risk Reduction Benefits of New Cervical Cancer Screening Technologies" appeared in Volume 13, No.1 of Focus. Mr. Sidoti has served as a consultant for laboratories and new technology cervical screening companies and laboratories, including Quest Diagnostics Incorporated, Teterboro, NJ and Digene Corporation, Gaithersburg, M.D.

Most simply stated, the standard of care or "standard of practice" is the standard practice followed by the reasonably qualified practitioner (gynecologist, cytotechnologist or pathologist) in the community. The simplicity of this definition belies its true complexity. In the risk management realm, "standard of care/practice" is a concept ripe with potential for manipulation and modification, and certainly represents a "moving target" for those seeking to comply with the accepted standards and minimize risk. Moreover, it is important to appreciate that the concept of a local "community" has been increasingly eroded and, with the advent of the internet and increased information sharing, replaced by the concept of a national, and in some cases, an international one. This is particularly the case in cervical cancer and cytopathology litigation, which, in most instances, applies a "national community" standard of care to the actions of laboratory professionals and clinicians alike. As in most medical realms, there are several primary sources of the "standard of care" in gynecology and cytopathology:

- Regulations and Standards
- Learned Treatises, Articles and Guidelines
- The Opinions of Litigation "Experts"
- Individual Clinical Practices
- Advancements in Testing Technology

As with any heavily regulated industry, laboratory science carries with it a complex network of standards, laws and guidelines which form a substantial part of the "standard of care" brought into sharp focus by the American judicial system. Indeed, due to the publicity of the late 1980s, which spawned the first Bethesda conference and significant updates to the CLIA regulations, cervical cytopathology is perhaps the most highly regulated aspect of laboratory science.

The CLIA Amendments of 1988 of course set the regulatory stage for cervical cytopathology. Almost all state legislatures have either adopted the CLIA regulations wholesale, or enacted their own standards for cervical cytopathology practice. In some cases, such as New York, these standards are more stringent than those in CLIA. CLIA regulates virtually all aspects of cervical cytopathology practice, from the qualifications of Lab Directors and Technical Supervisors, to the guidelines for retrospective review and corrective reports, to quality control and assurance requirements, to the number of slides cytotechnologists may screen in an 8 hour workday. Many of these regulations have themselves spawned endless expert debate and infighting in the highest ranks of the cytopathology community regarding their proper interpretation and application. One example is the 5 year retrospective review requirement, which many argue does not require laboratories to make a verbatim (and potentially discoverable) record of actual assessment modifications unless the modifications fulfills the criteria for issuance of a corrective report, a relatively rare circumstance. Others contend that such records should be maintained.

In the field of gynecology, practice and technical bulletins and published guidelines (now often available to the general public via website postings) adopted by leading organizations such as the American College of Obstetrics and Gynecology (AGOG), and the American Society for Colposcopy and Cervical Pathology (ASCCP), are often looked to as a guide to establish the standard of care.

Learned Treatises, Articles and Guidelines

In both fields, excerpts from so called "learned treatises" (such as Richard De May's "The Art & Science of Cytopathology" and Hoskin's "Principles and Practices of Gynecologic Oncology") are commonly cited as establishing the accepted standards in the community. Peer reviewed Journals, such as ACOG's Green Journal and ASCCP's Journal of Lower Genital Tract Disease, provide additional sources.

As one might imagine, the vast amounts of information, data, analysis and opinion contained in these innumerable resources make establishment of, and compliance with, unified standards immensely difficult. Moreover, cross-over application of many of these guidelines complicates the matter. For example, the Guidelines for Review of Pap Smears in the Context of Litigation, adopted several years ago by the College of American Pathologists and American Society of Cytopathology (and subsequently by many state cytopathology organizations), establish guidelines which bear upon the appropriateness of retrospective Pap smear review in a legal context. These address the precise issue of whether certain discrepancies noted in such a context should reasonably form the basis for a claim of deviation form accepted standards. While at first blush these Guidelines appear applicable only to the practice of cytopathology, there is a very real correlation between the risk of laboratory litigation they seek to contain, and the involvement of gynecologists in the same potential lawsuits. Simply put, if, as the Guidelines make clear, disputed cases

Continued on page 7

Continued from page 6

of ASCUS should not form the basis for a claim of deviation, less filings against both laboratories and gynecologists will result.

The Opinions of Litigation "Experts"

Additionally, the role of the litigation expert's opinion in framing the standard of care should never be minimized. Much has been written regarding the need for ethical and professional ramifications for practitioners who advocate untenable or not generally accepted theories of liability in a litigation context. Indeed, most organizations - including ACOG and CAP - have sought to control this problem through the issuance of voluntary guidelines, like those noted above. Unfortunately, most attempts have been unsuccessful; policing large groups of professionals in the application of national standards is a monumental undertaking, made even more difficult when the disciplines involved are the subject of intense and, at times, controversial regulatory schemes. Of course, the plaintiff's bar in the United States, long known as the strongest and most influential political lobbying organization in the Country, places significant obstacles to maintaining control over expert opinion at every turn. In short, it appears for the foreseeable future that there will always be "experts" willing to argue the inapplicability of accepted practices and guidelines -- or, in fact, that certain practices and guidelines are not generally accepted -- in support of what would otherwise be tenuous legal claims. The real danger here, however, is that in the microcosm of the individual lawsuit, these opinions, if ultimately given more weight by a jury than opposing views, are capable of establishing a standard of care that affects not only the lawsuit at hand, but future cases.

Individual Clinical Practices

Against this complex and interconnected framework of evolving regulations, guidelines, and expert opinion, the practitioner's own standards also play a role. Most gynecologists have developed and attempted to uniformly apply standards of practice in the context of cervical cancer detection and treatment. In most instances, these standards comply with those generally accepted in the "national community," as derived from the learned treaties and peer-reviewed sources mentioned above. For those who fail to practice in accordance with these standards, the implications are obvious. Less apparent, perhaps, are the hidden pitfalls of failing to comply with self-created standards which exceed those that have attained formal adoption status in the community. This is the classic application of something that "gives with one hand, yet takes away with the other." By way of example, many practitioners institute specific protocols for notification of patients with abnormal (and in some cases, normal) cytopathology results. This is clearly a laudable practice, although not one that is the subject of significant regulation. Clearly, providing specific notification to patients at increased risk of the need for follow up care can significantly reduce litigation risk to the clinician. On the other hand, such voluntary practices establish personal standards of care which can be used to establish deviation when, through a clerical oversight or otherwise, an at-risk patient does not receive her postcard in the mail urging her to return for follow up.

Advancements in Testing Technology

Finally, newly developed and proven technologies that enhance the practitioner's ability to accurately assess the presence or absence of disease and institute appropriate follow up care or treatment may also establish the standard of care. The fundamental premise is not difficult to understand - treatises and practice guidelines in the medical arena all derive from proven practices and treatment protocols. In the field of medical testing, those tests that provide the greatest sensitivity and specificity will become the standard that the general public and the medical community expect will be offered to the patient population. Where the accepted tests at issue have well-recognized limitations - for example PSA, mammography, and, of course, the conventional Pap smear - public and academic attention will constantly be focused on enhancements which are proven to reliably increase the efficacy of the underlying test. When such technologies are discovered, tested and proven effective, and certainly when they are recognized by national regulatory and standard setting organizations such as the FDA, it quickly becomes expected that clinicians will not only be knowledgeable about them, but make them available to their patient populations. While newly recognized and approved technologies will always have learned detractors and skeptics, effective risk management protocols and the concept of informed consent require the prudent practitioner to be aware of these enhancements and, where appropriate, offer them to their patients. These patients will be first to remind the clinician -- often in the context of a malpractice suit following an adverse outcome -- that the best available testing/care was not provided.

This is particularly the case in the field of cervical cancer detection. For years, the limitations of the conventional Pap smear have been the subject of vast media attention and sharp legal focus. Against that background, the development and marked success of liquid based cytology, credited with dramatically improving sensitivity and reducing the limitations associated with conventional preparations, has reached the point where many would argue that this testing (or at least education of the patient as to the availability of this test) is, in fact, the standard of care in cervical cancer screening.

Clearly, advances in gene-based HPV detection and the implications of these advances for assessing the cervical cancer risk status of women are following a similar path. Adoption of the FDA approved uses of gene-based HPV testing in cervical cancer detection regimen would appear to provide clinicians with an effective approach to risk control in future litigated matters, even in advance of unquestionable standard of care consensus in the community. In fact, clinicians who feel that "standard of care" status for this technology has not yet been formally attained may effectively argue that they went "above and beyond" the formally recognized standards in offering or providing such testing to their patients, but -- critically -- did so in a prudent manner given the proven efficacy and the FDA's formal approval of this testing.

While the health of their patient population is always paramount in this analysis, the relationship of addressing this paramount concern to the reduction of liability risk for the practitioner should be apparent. In sum, performing or offering patients gene-based HPV testing within the FDA approved parameters provides the following benefits:

- Allows the clinician to reduce the overall number of cervical cancer incidents which, in addition to clearly benefiting the patient population, significantly reduces the risk of being involved in a malpractice suit arising out of a cervical cancer diagnosis;
- Reduces reliance on the imperfect Pap test alone to determine risk status of the patient;
- Minimizes the effect of imperfect, patient-provided cytology and gyn symptomatology history in the risk assessment process;
- May minimize the effect of imperfect annual follow up by patients

Continued on page 8

Continued from page 7

(although this is somewhat offset by the increased possibility of patients being lost to follow up as a result of the extended pap smear interval when concurrent HPV screening and pap results are both negative); and

- Provides the clinician with the ability to claim that the newest approved and proven effective technology was used (or offered) and supports the clinician's position that he or she has practiced consistent with the highest standard of care.

While adhering to these suggestions will certainly not result in perfect patient care or fully insulate even the most prudent clinicians from liability, one thing is certain: failure to do so puts the clinician at increased risk if cancer develops during the process of screening with less sensitive tests.

EXPERT'S CORNER

Endoscopic Ultrasound Guided Fine Needle Aspiration Biopsy of the Pancreas:

A Morphology Primer.

PART II. CYSTIC MASSES

Martha Bishop Pitman, M.D.

Massachusetts General Hospital, Boston, MA

Pancreatic cysts are uncommon compared to solid masses with only about 10% of pancreatic neoplasms represented by this category. The most important job for the pathologist is to distinguish non-neoplastic cysts that can be medically managed from neoplastic cysts that are typically resected. Mucinous cysts are especially important to recognize given their malignant potential. The new 4th series AFIP fascicle, *Tumors of the Pancreas* (in press), subclassification of the most common primary pancreatic cysts is as follows:

Pseudocyst

Serous cystadenoma

Mucinous cystic neoplasm (MCN)

- ➢ Mucinous cystic neoplasm with low grade dysplasia (adenoma)
- ➢ Mucinous cystic neoplasm with moderate dysplasia
- ➢ Mucinous cystic neoplasm with carcinoma in-situ
- ➢ Mucinous cystic neoplasm with invasive carcinoma

Intraductal papillary mucinous neoplasm (IPMN)

- ➢ Intraductal papillary mucinous neoplasm with low grade dysplasia (adenoma)
- ➢ Intraductal papillary mucinous neoplasm with moderate dysplasia
- ➢ Intraductal papillary mucinous neoplasm with carcinoma in-situ
- ➢ Intraductal papillary mucinous neoplasm with invasive carcinoma

This list includes only those primary pancreatic cysts most commonly encountered by endoscopic ultrasound guided biopsy (EUS-FNAB). Solid tumors that become cystic secondarily should always be considered in the evaluation of an aspiration of a cystic mass lesion, but inclusion of them here is beyond the scope of this brief review.

A multimodal approach is particularly important in the interpretation of pancreatic cysts. Combining the clinical, EUS features, gross cyst fluid, special stains for mucin and cyst fluid analysis for amylase and CEA can greatly enhance the overall cytological interpretation.

Pseudocyst

A pancreatic pseudocyst is a localized collection of pancreatic secretions, necrotic debris and blood, that by definition, has no epithelial lining. Pseudocysts occur as a consequence of damage to the pancreatic parenchyma that results in hemorrhage, necrosis and autodigestion of pancreatic tissue from the release and activation of pancreatic enzymes. This pancreatic injury and, thus incidence, is most common in patients with alcohol abuse. Approximately 10% of patients with acute pancreatitis will develop a pseudocyst. The age and gender of patients with pseudocysts parallels that of pancreatitis. Alcohol related pseudocysts are more common in middle-aged men while pseudocysts secondary to trauma, biliary disease and heredity pancreatitis are relatively equal in men and women. Pseudocysts can be complicated by rupture, hemorrhage due to erosion into a vessel, obstruction of surrounding structures and infection. Pseudocysts may be medically managed, but most are drained or resected.

Pseudocysts are usually solitary, small to very large (up to 20 cm), well-demarcated, thin walled, unilocular, non-septated, mostly peripancreatic cysts that can occur anywhere in the pancreas, but are most common in the pancreatic tail.

The cyst fluid aspirated from an uncomplicated pseudocyst is generally thin, clear or brown to green and non-mucinous. A complicated pseudocyst, however, may produce thick mucoid appearing fluid due to the presence of inflammation. Cytologically, the characteristic features include degenerative cyst debris with acute and chronic inflammatory cells, histiocytes, hemosiderin and often bile (Figure 1). By definition, there are no cyst lining epithelial cells. Care must be taken not to misinterpret histiocytes as epithelial cells. Contamination of injured

Continued on page 9