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Error reduction and risk management in cytopathology

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Currently, tort reform is not a major priority in either the Congress of the United States or in state legislatures. Thus, it is fortunate that medical negligence claims against pathologists are relatively infrequent, at 8.3% per year per 100 insured pathologists (data from the Doctors' Company, 2000-2003). However, claims for "missed" cervical cytology specimens rank third, behind those for alleged misinterpretation of breast biopsies and pigmented skin lesions. The severity of cervical cytology errors is high, at almost $700,000 per claim, surpassed only by those concerning melanoma. There are common threads that appear consistently in the analysis of slides from allegedly misdiagnosed cervical cytology cases, including small-cell variants of high-grade squamous intraepithelial neoplasia (HGSIL), present in small numbers; hyperchromatic crowded cell groups; atypical squamous cells of undetermined significance (ASCUS); smears taken during menses; other bloody smears, particularly with degenerative features or excessive inflammation; others showing atypical repair; and unsatisfactory samples. It is important for pathologists to spend time with cytotechnologists to emphasize the patterns of abnormal smears at low microscopic magnification and those backgrounds featuring blood and inflammation which require particular attention. Managing the "look-back" requirement of the Clinical Laboratory Amendments of 1988 (CLIA88) is also crucial; the need to issue amended reports as a consequence of that provision is quite rare. Procedures for administrating and reporting retrospective reviews under the CLIA88 should be clearly outlined in a peer-reviewed procedure document in each laboratory. They should be reviewed and approved by risk managers or insurance carriers, and documented in such a manner that one obtains maximal protection from legal discovery. Consumer education is particularly important in maintaining laboratory performance and reducing risk from error in cytology. Periodic feedback to clinicians on the quality of their smear preparations, the use of ancillary techniques (eg, human papillomavirus testing), and discussion of reporting terminology are important. Moreover, one should stress the need for pertinent clinical history that is often required to initiate quality control measures for evaluation and reporting of cervical cytology specimens. The incidence of cervical cancer in the United States, at only 9700 new cases per year, is low, emphasizing the need for clinical vigilance, attention to unexplained symptoms and signs, and biopsies of any cervical abnormality. These and other efforts may assist in reducing the risk of litigation attached to allegedly false-negative gynecologic and nongynecologic cytology samples.

With the publication of a report from the Institute of Medicine on medical error in the United State in late 1999 (To Err is Human: Building a Safer Health Care System), there has been a major effort to address this topic meaningfully.[1] Despite increased activity in nearly all facets of the American Health Care System, including additional accreditation requirements of the Joint Commission on Accreditation of Health Care Organizations (JCAHO)[2] to improve error identification and reporting, similar efforts at national

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tort reform have been minimal. That omission is a major impediment to open discussion and analysis of medical error. For example, a Congressional bill (S.1784), introduced in September of 2005, mandating systematic reporting of medical error and cosponsored by two aspiring 2008 presidential candidates (Senators H. Clinton and B. Obama), contained no safeguards from exposure to medical liability.[3] The 109th Congress of the United States closed out its session in 2006 with no meaningful action on tort reform, and there is no indication that the 110th Congress has tort reform anywhere on its agenda.

In the broad context of medical risk management, pathologists have been fortunate to be at low risk for malpractice actions. However, when alleged negligence is claimed in our specialty area, its severity can be marked, particularly for cervical cytology cases, which have often had high profiles. Since its introduction in the early 1950s, the Papanicolaou (Pap) smear has been promoted as a successful "failsafe" test to avoid death from cervical cancer.[4] Although the historical reduction in death from cervical cancer has been dramatic (at least 70%), that diminution occurred primarily in the first 15 years of the widespread use of cervical cytology and has remained essentially stable, without further improvement, to the present time. It is also estimated that 60% of women currently diagnosed with invasive cervical cancer have either never had a cervical cytology examination or have not had one in the 5 years before their diagnosis.[5] Failure of cytologists to make the shortcomings of cervical cytology known to both clinicians and the public has led victims of allegedly "missed" cervical smears to seek redress through the tort system.[4] They typically make emotionally sympathetic plaintiffs because they are usually young and either dead or badly injured from cervical cancer.

The rising numbers of malpractice actions against pathologists was first noted by Troxel and Sabella in 1994. They reported on data from the Doctor's Company, a major medical liability insurer of pathologists, showing that the loss ratio had risen from 0.3% in 1987 to 202.5% in 1993.[6] It was also found that the numbers of claims against pathologists had remained steady during this same period, at 9 per 100 pathologists per year. More recent data ranks gynecologic cytology behind breast pathology and melanoma, with regard to the number of claims against pathologists each year. In reference to the degree of severity of an individual claim, gynecologic cytology ranks second behind melanoma cases, but it is very close in dollars paid in legal awards for alleged errors of pathologic interpretation.[7] A much smaller percentage of claims in cytology concerns fine needle aspiration biopsy of the breast. Most of the remaining claims involving surgical pathology center on the interpretation of breast and prostate core needle biopsies and the diagnosis of lymphoma.[6] This topical distribution has remained relatively stable over time.

Troxel has systematically published information based on claims reviews, indicating areas where pathologists are vulnerable and recommending steps to reduce the risk of liability.[8–13] Table 1 lists a summary of claims based on disease or anatomic site and their distribution regarding false-negative or false-positive errors.[13] There is a clear message in those data for the pathologist to read gynecologic cytology and pigmented skin lesions aggressively (ie, favoring the possible overdiagnosis of malignancy), avoiding allegedly false-negative results. Most of the other entries in Table 1 are split relatively evenly between false-negative and false-positive errors, but the numbers of cases are small.

Table 1 Pathology claims, 1998-2003, for false-negative and false-positive cancer reports

Specimen type	False-negative no. (%)	False positive no. (%)
Melanoma	42 (95%)	2 (4.5%)
Breast biopsy	0 (48%	22 (52%)
FNA of breast	2 (40%)	3 (60%)
Gyn cytology	41 (98%)	1 (2%)
Sarcomas	12 (80%)	3 (20%)
Lymphomas	8 (57%)	6 (43%)
Lung pathology	5 (42%)	7 (58%)
Prostate biopsies	6 (67%)	3 (33%)

From Troxel D: An insurer's perspective on error and loss in pathology. Arch Pathol Lab Med 129:1234-1236, 2005.

The practice of gynecologic cytology has also remained a highly visible risk, as dramatized in the news media, including at least one case in which criminal charges were filed.[14] In the Doctors' Company data, gynecologic cytology cases accounted for approximately 20% of reserve (unpaid) losses and 14% of paid losses.[15]

The ability of the pathology community to assess this problem globally has been hampered by a lack of data from other medical malpractice insurers. However, a recent presentation at a workshop given by the Physician Association of America (PIAA) on medicolegal claims reported that between 1985 and 2005, $53,397,200 had been paid in indemnity for cervical cytology-based actions.[16] The overarching nature of this risk management problem is evident. Over the last several years, major underwriters of malpractice insurance have either left the field or gone bankrupt. Doctors have also retired early, moved their practices from states without "caps" on legal awards, or abandoned the practice of "high-risk" specialties such as obstetrics. Physicians have also vigorously lobbied state legislatures and the U.S. Congress for tort reform, but with very limited success.

Problems with gynecologic cytology are not new. Both the American Society of Cytopathology (ASC) and the International Academy of Cytology (IAC) have called attention to issues of quality control and quality assurance in cytology laboratories as far back as 1966.[17] In 1975, the ASC Presidential address of Dr. Stanley Inhorn reviewed the history of government regulation of laboratories, including cytology, and called on the profession to renew their commitment to high standards of cytology practice.[18] In