An Insurer’s Perspective on Error and Loss in Pathology

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Objectives.—To identify errors in surgical pathology practice that lead to malpractice claims, and to define the frequency and severity of pathology malpractice claims and discuss the implications.

Design.—Three hundred seventy-eight pathology malpractice claims reported to The Doctors Company of Napa, Calif, between 1998 and 2003, were reviewed. Nuisance claims and autopsy claims were excluded; the 335 remaining claims were analyzed.

Results.—Pathology claim frequency is low. Pathology claim severity is high, especially for claims involving a misdiagnosis of melanoma or a false-negative Papanicolaou test. Fifty-seven percent of claims involved the following 5 categories: breast specimens, melanoma, Papanicolaou smears, gynecologic specimens, and operational error. Sixty-three percent of claims involved failure to diagnose cancer, resulting in delay in diagnosis or inappropriate treatment.

Method.—A false-negative diagnosis of melanoma is the single most common reason for filing a malpractice claim against a pathologist. Nearly one third of misdiagnoses involve melanoma misdiagnosed as Spitz nevus, “dysplastic” nevus, spindle cell squamous carcinoma, atypical fibroxanthoma, and dermatofibroma.

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The clinically significant diagnostic error rate in surgical pathology reported in the literature varies from 0.26%1 to 1.2%,2-5 when uncovered by prospective review of all cases or when a random sample of cases is reviewed. A blinded review of 5000 sequential biopsies revealed a clinically significant error rate of just 0.08%.6 Thus, surgical pathology has a relatively low diagnostic error rate.

There are many ways to define the term error in surgical pathology.7,8 Our judicial system defines medical error as injury resulting from negligence. Negligence is defined by expert testimony as medical practice that falls below the standard of care. Standard of care is the professional behavior expected of a prudent, careful, and informed physician; it is a national standard, not a “community” standard, and is difficult to differentiate from “best practices.” Finally, the injury must be a consequence of the negligent professional behavior, that is, negligence must be the proximate cause of injury.

Patients who believe they have been injured as a consequence of a pathologist’s diagnostic error (resulting in an inappropriate treatment or a delay in diagnosis), may file a malpractice claim. Thus, a review of the causes of malpractice claims is yet another way of identifying error, error as defined by society and the judicial system.

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METHODS
The Doctors Company (TDC) is a physician-owned professional liability insurance company based in Napa, Calif. The Doctors Company insures about 1100 pathologists practicing throughout the United States. Consequently, its claims experience should be a representative sample of all pathology claims, and an analysis of the diagnostic and operational errors leading to these claims should be a reflection of problems that occur in many pathology practices.

Claims frequency is the number of claims reported each year per 100 insured physicians. As a specialty, pathology has a low claims frequency. From 2000 to 2003, on average, a claim was filed each year against 8.3% of TDC’s insured pathologists. Stated differently, the average pathologist had a claim every 12 years. Claims severity is the average indemnity plus the loss-associated expense paid per closed claim. Pathology has high severity, because many pathology claims result from the failure to diagnose cancer. From 2000 to 2003, the average TDC claim severity for all pathology claims was $453 201, whereas melanoma claims severity was $757 146 (95% involved a false-negative diagnosis), Papanicolaou test claims severity was $686 599 (98% were false-negatives), and breast cancer claims severity was $203 192 (false-negatives and false-positives were evenly divided).

RESULTS AND COMMENT
To identify repetitive patterns of specimen type or diagnostic category, 378 pathology claims reported to TDC from 1998 through 2003 were reviewed. When nuisance claims (9.5% of total) and claims involving autopsies (2% of total) were excluded, 335 claims remained and are categorized in the Table.

Of the 335 claims studied, 14.5% were surgical pathology claims showing no particular pattern relating to specimen type, diagnostic category, or diagnostic error; these claims represented random errors.9 Within this miscellaneous surgical pathology category, 5 claims resulted from missed infectious agents (Coccidioides immitis, tuberculosis, Aspergillus, leprosy, and chorioamnionitis), and 1 claim
involved “missed” brain tissue admixed with sinus contents, indicating surgical perforation of the sinus.

The remaining 85.5% of pathology claims fell into repetitive patterns of specimen type or diagnostic category, suggesting systematic errors (see Table). Overall, 63% of these claims involved the false-negative diagnosis of cancer and 22% involved the false-positive diagnosis of cancer. More than half of the claims (57%) involved melanoma, breast specimens, Papanicolaou tests, gynecologic specimens, and operational errors.

Of the 42 false-negative melanoma claims, 29% were melanomas misdiagnosed as Spitz nevi (n = 3), “dysplastic” nevi (n = 3), spindle cell squamous carcinoma (n = 3), and atypical fibroxanthoma (n = 1); 2 were unrecognized desmoplasic melanomas. The misdiagnosis of melanoma is a continuing problem for pathologists and has become the single most common reason for filing a claim against a pathologist. This difficult area of differential diagnosis needs to be emphasized in both residency training and continuing medical education programs.10,11

Of the 42 breast biopsies, 79% were excisional biopsies and 21% were cutting needle biopsies. Four involved the misdiagnosis of ductal carcinoma in situ, 1 of lobular carcinoma in situ, and 2 involved lymph node metastases that were missed. While breast biopsy claims are a close second to melanoma, when combined with breast fine-needle aspiration and breast frozen section claims, breast specimens account for 15.5% of all claims and are the most common cause of pathology malpractice claims.12 Breast biopsy claims are almost evenly divided between false-negatives and false-positives.

In a review of claims from 1995 to 1997, most breast fine-needle aspiration claims were false-negatives resulting from sampling error, typically in a woman with a palpable breast mass subsequently diagnosed as carcinoma. False-positive breast fine-needle aspirations were usually interpretation errors, typically a fine-needle aspiration diagnosis of carcinoma made on a fibroadenoma.13,14 The current data show a decrease in the number of breast fine-needle aspiration claims. Whether this represents improved practice performance or an increased preference for cutting needle biopsy cannot be determined.

Of the 31 gynecologic pathology claims, 13 claims (42%) involved misdiagnosed ovarian tumors. Eleven (85%) of these 13 claims were false-negative diagnoses of malignancy, and 2 (6%) were false-positives.

Twenty-two (6.5%) of the total 335 claims involved specimen operational errors. Thirteen claims (59%) involved specimen mix-ups resulting in one patient getting an incorrect malignant diagnosis and another getting an incorrect benign diagnosis. Eighty-five percent (n = 11) of these claims involved breast (n = 7) or prostate (n = 4) needle biopsies, 1 was a lung biopsy, and 1 was a gastric biopsy. Three claims were for lost breast needle biopsies. Three involved floaters (prostate, colon, and lymph node fragments). Two involved mislabeled biopsy sites. One claim was a transcription error (failure to type “no” in front of “malignant cells identified”).

Of the 12 claims involving the false-negative diagnosis of sarcoma, 4 (33%) were monophasic synovial sarcomas.

Of the 8 claims involving the false-negative diagnosis of lymphoma, 5 (63%) were extranodal lymphomas. Of the 6 claims involving a false-positive diagnosis of lymphoma, 2 were extranodal reactive hyperplasias and 1 was a melanoma metastatic to lymph node. The extranodal sites included breast, stomach, bone, nasopharynx, rectum, and parotid. Overall, 50% of lymphoma claims involved extranodal lymphomas or reactive hyperplasias.15

Of the gastric biopsy claims, 4 of the 5 false-negatives involved signet ring cell carcinoma, as did 1 of the 7 false-positives.

Fifteen (4.5%) of the total 335 claims involved frozen section misdiagnoses, and one third of these were breast frozen sections.

Seven (2%) of the total 335 claims involved false-negative diagnoses of malignant salivary gland tumors (most were misdiagnosed as pleomorphic adenoma).

Five (1.5%) of the total 335 claims involved the appendix; 2 of these were missed mucinous cystadenocarcinomas, and 1 involved a colonic diverticulum for the appendix.

There has been a significant decrease in the number of miscellaneous fine-needle aspiration claims, which probably represents greater practice experience with this diagnostic technique.

The failure to diagnose carcinoma in situ (high-grade intraurothelial neoplasia) of the urinary bladder is an ongoing problem, as is the misdiagnosis of metastatic squamous carcinoma in a cervical lymph node as branchial cleft cyst.16

Claims involving prostate needle biopsies remain relatively infrequent. Two thirds of these claims involve the failure to diagnose carcinoma, whereas in a previous review, more than two thirds of claims involved a false-positive diagnosis of carcinoma.15 This shift may reflect pathologist’s greater familiarity with the mimics of carcinoma (partial atrophy, adenosis, etc).

Claims for false-negative Papanicolaou tests have decreased from 17% of total claims in 1995–1997 to 12.5%, and are now third in frequency behind melanoma and breast claims.
References