

Trends in Pathology Malpractice Claims

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Abstract: Previously reported analyses of pathology malpractice claims reported to The Doctors Company from 1995 through 2003 uncovered repetitive patterns of specimen type and diagnostic category that contributed to claims. To determine whether these patterns had changed, 276 pathology malpractice claims from 2004 through 2010 were reviewed and are the subject of this report. Claims involving melanoma, breast (specimens and fine needle aspiration), system error, gynecologic cytology, and fine needle aspiration (excluding breast) accounted for 49% of the total claims. There has been a significant decline in the number of claims involving melanoma, breast, and gynecologic cytology, and the factors contributing to this decline are discussed.

Key Words: pathology malpractice, pathology claims, pathology errors

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The Doctors Company is a physician-owned professional liability insurance company headquartered in Napa, California. It is the nation's largest insurer of physician and surgeon liability. Almost 1400 pathologists practicing throughout the United States are members of The Doctors Company; therefore, their claims experience should be a representative sample of all pathology claims, and an analysis of the diagnostic and system errors leading to the adverse events in these claims should be a reflection of errors that occur in many pathology practices.

To identify repetitive patterns of specimen type or diagnostic category contributing to pathology claims, 344 closed claims from The Doctors Company from 1995 through 1997 were reviewed (Table 1) and have been previously reported.^{1,2} Subsequently, 378 additional closed claims from 1998 through 2003 were reviewed (Table 2) and reported.^{3–6} To ascertain whether there have been changes in the previously identified patterns of specimen type and diagnostic category, 276 closed pathology claims from 2004 through 2010 were reviewed and are the subject of this report.

From the The Doctors Company, Napa, CA.

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MATERIALS AND METHODS

Only claims closing with payments of indemnity and/or loss-adjustment expense (legal defense costs and expert witness fees) were reviewed. Frivolous and companion claims (44% of the total) were excluded. Frivolous claims closed without payment of indemnity and included claims with absurd or questionable allegations, claims dismissed or dropped, and claims that named every doctor in the medical record. Also excluded were claims naming the pathologist as a codefendant because he or she performed an autopsy (4.7%); none of those claims paid indemnity, and the pathologist was never the focus of the claim. The remaining 142 pathology claims are the subject of this analysis (Table 3).

This review spans 7 years from 2004 through 2010. The prior review of claims from 1998 through 2003 spanned 6 years, and the review of claims from 1995 through 1997 spanned 3 years. To compare changes in claim “frequency” between these 3 analyses, the total number of claims in each study was divided by the total number of years in the study to arrive at an average “claims per year” calculation. It is important to note that this number is not the actual number of claims in each year; it is an average.

RESULTS

Definitions

A claim is a demand for payment. Claim frequency is the actual number of claims reported each year per 100 insured physicians. Pathology is a low-frequency specialty (6% of our insured pathologists had claims in 2009). Claim severity is the average indemnity and loss-adjustment expense per closed paid claim. Pathology is a high-severity specialty due to failure to diagnose cancer, resulting in a delay in diagnosis and/or inappropriate treatment. For claims closing from 1999 through 2010, the average severity for all pathology claims was \$431,964. The average severity for melanoma claims was \$753,100 and that for gynecologic cytology claims was \$596,455 (Table 3).

A professional liability claim results from 3 factors: negligence, injury, and anger. Negligence is defined by expert testimony as a medical practice that falls below the standard of care. One may characterize standard of care as the professional behavior expected of a prudent, careful, and informed physician. It is my impression that pathologists are often held to a higher standard of care than other physicians. We are viewed as “the doctors’ doctor,” rendering a “final diagnosis” achieved through

TABLE 1. Two Hundred Ninety-Two Pathology Claims Closed From 1995 Through 1997

Specimen Category	Total Claims	Claims per Year	% (#) False Negative (Cancer)	% (#) False Positive (Cancer)	% Total Claims
Miscellaneous surgical pathology	97	32.3	50% (51)	18% (18)	33.2
Gynecologic cytology	59	19.7	Virtually 100%*	—	20.2
Breast specimens	31	10.3	55% (17)	35% (11)	10.6
Melanoma	23	7.7	70% (16)	4.0% (1)	7.9
FNA, miscellaneous	16	5.3	19% (3)	56% (9)	5.5
Lymphoma	16	5.3	75% (12)	19% (3)	5.5
FNA, breast	12	4.0	58% (7)	33% (4)	4.1
Clinical pathology	11	3.7	N/A	N/A	3.8
Frozen sections	10	3.3	40% (4)	40% (4)	3.4
Prostate biopsy	9	3.0	22% (2)	78% (7)	3.0
Nongynecologic cytology	4	1.3	N/A	N/A	1.4
System error	4	1.3	N/A	N/A	1.4

I reviewed 344 of The Doctors Company's pathology claims closing from 1995 through 1997. Frivolous claims (13%) and autopsy claims (2%) were excluded. A total of 292 claims remained and are the subject of this analysis.

When gynecologic cytology claims were included (which almost always involve false-negative diagnoses), 59% of these claims involved the false-negative diagnosis of cancer, and 20% involved the false-positive diagnosis of cancer. Claims involving gynecologic cytology, breast (specimens and FNA), melanoma, and system error accounted for 44.2% of total claims.

*Exact count not retrievable.

FNA indicates fine needle aspiration.

the objective microscopic observation of tissues and cells—in contrast to the subjectivity and “art” of clinical decision making. Finally, patient injury must be the consequence of negligent professional behavior (“causation”).

DISCUSSION

Claims involving melanoma, breast [specimens and fine needle aspiration (FNA)], system error, gynecologic cytology, and FNA (excluding breast) account for 49% of the total claims. There has been a significant decline in the number of claims involving melanoma, breast, and gynecologic cytology, which together account for 31% of the total claims.

Melanoma claims have decreased from 7.7 claims per year from 1995 to 1997 and 7.3 claims per year from 1998 to 2003 to 2.4 claims per year from 2004 to 2010. However, a false-negative diagnosis of melanoma is still the most common reason for filing a malpractice claim against a pathologist. Two of the 16 false negatives were melanomas misdiagnosed as Spitz nevus; this differential diagnosis continues to be a diagnostic challenge, and pathologists should be hesitant to diagnose Spitz nevus in an adult without seeking expert opinion.⁷ Many claims would be prevented by recommending (in the report) complete excision of an “atypical melanocytic proliferation.” Failure to completely excise a “missed” melanoma is often the alleged causation of a subsequent metastasis.

TABLE 2. Three Hundred Thirty-Five Pathology Claims Closed From 1998 Through 2003

Specimen Category	Total Claims	Claims per Year	% (#) False Negative (Cancer)	% (#) False Positive (Cancer)	% Total Claims
Miscellaneous surgical pathology	48	8.0	65% (31)	19% (9)	14.5
Gynecologic cytology	42	7.0	98% (41)	2% (1)	12.5
Breast specimens	42	7.0	48% (20)	52% (22)	12.5
Melanoma	44	7.3	95% (42)	4.5% (2)	13.0
Fine needle aspiration, miscellaneous	10	1.7	40% (4)	60% (6)	3.0
Lymphoma	14	2.3	57% (8)	43% (6)	4.0
Fine needle aspiration, breast	5	0.8	40% (2)	60% (3)	1.5
Clinical pathology	17	2.8	—	—	5.0
Prostate biopsy	9	1.5	67% (6)	33% (3)	2.5
Nongynecologic cytology	4	0.7	100% (4)	—	1.0
System error	22	3.7	—	—	6.5
Gynecologic pathology	31	5.2	74% (23)	16% (5)	9.5
Sarcomas	15	2.5	80% (12)	20% (3)	4.5
Lung pathology	12	2.0	42% (5)	58% (7)	3.5
Gastric biopsy	12	2.0	42% (5)	58% (7)	3.5
Bladder CIS	5	0.8	100% (5)	—	1.5
BCC	3	0.5	100% (3)	—	1.0

I reviewed 378 of The Doctors Company's pathology claims closing from 1998 through 2003. Frivolous claims (9.5%) and autopsy claims (2%) were excluded. A total of 335 pathology claims remained and are the subject of this analysis.

Of these claims, 63% involved the false-negative diagnosis of cancer, and 22% involved the false-positive diagnosis of cancer. Claims involving gynecologic cytology, breast (specimens and FNA), melanoma, and system error accounted for 46% of the total claims.

CIS indicates carcinoma in situ.

TABLE 3. One Hundred Forty-Two Pathology Claims Closed From 2004 Through 2010

Specimen Category	Total Claims	Claims Per Year	% (#) False Negative (Cancer)	% (#) False Positive (Cancer)	% Total Claims
Miscellaneous surgical pathology	23	3.3	—	—	16.2
Gynecologic cytology	10	1.4	100% (10)	None	7.0
Breast specimens	15	2.1	40% (6)	46.7% (7)	10.6
Melanoma	17	2.4	94% (16)	6.0% (1)	12.0
Fine needle aspiration, miscellaneous	10	1.4	—	—	7.0
Lymphoma	1	0.1	—	—	0.7
Fine needle aspiration, breast	2	0.3	—	—	1.4
Clinical pathology	8	1.1	—	—	5.6
Nongynecologic cytology	3	0.4	—	—	2.1
System error	15	2.1	N/A	N/A	10.6
Gynecologic pathology	6	0.9	—	—	4.2
Sarcomas	5	0.7	—	—	3.5
Lung pathology	6	0.9	—	—	4.2
Gastric biopsy	3	0.4	—	—	2.1
BCC	5	0.7	100% (5)	—	3.5
Colon	7	1.0	—	—	4.9
Frozen section	6	0.9	—	—	4.2

There are probably several reasons for this significant drop in claims involving melanoma misdiagnosis:

- Over the past decade, there have been many publications in the pathology literature, continuing medical education (CME) programs sponsored by national and state pathology societies, and grand round presentations to residents and large pathology groups that have focused on melanoma diagnosis and misdiagnosis. I believe that these have made pathologists more aware of the difficulties inherent in melanoma diagnosis and perhaps more likely to seek second or expert opinion on difficult cases.
- In parallel with other medical specialties, pathologists are moving from small group to large group practices. Larger groups have workloads that justify adding pathologists with subspecialty training, particularly in dermatopathology and cytopathology, and a practice's dermatopathologist is apt to be consulted on difficult cases or to review all melanocytic lesions that are not typical nevi.

Breast (specimens and FNA) claims have decreased from 14.3 claims per year from 1995 to 1997 to 7.8 claims per year from 1998 to 2003 to 2.4 claims per year from 2004 to 2010. It is noteworthy that 2 of the 6 false-negative claims in this study involved immunohistochemical stain misinterpretations: 1 for ER and 1 for HER2. This significant decrease in breast biopsy claims probably reflects greater emphasis in the literature and in CME programs on directed needle biopsy interpretation, greater experience with this diagnostic technique, increased use of standardized protocols and diagnostic algorithms, and the decreased use of breast frozen section. None of the 6 frozen section claims in this study involved breast specimens. The near disappearance of breast FNA claims reflects the decreased use of this diagnostic procedure.

Gynecologic Cytology (Pap smear and Pap test) claims have decreased from 19.7 claims per year from 1995 to 1997 to 7.0 claims per year from 1998 to 2003 to 1.4 claims per year from 2004 to 2010. Two of the 10 false

negatives involved a diagnosis of “atypical gland cells of undetermined significance,” and 1 involved a diagnosis of “reactive endocervical cells” in women who were subsequently diagnosed with endocervical adenocarcinoma. The women were told that their Pap tests were “negative” (for “intraepithelial lesion or malignancy”), and there was no follow-up. In the 2 atypical gland cells of undetermined significance claims, expert reviewers felt that the atypical cells were suspicious for malignancy. The “reactive endocervical cells” claim resulted from failure of the pathologist to recommend follow-up colposcopy with endocervical sampling to the woman's primary care physician. It is important for pathologists to be familiar with the *2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests*, which states “the Pap test is not effective in detecting cervical adenocarcinoma. The abnormal cells are often interpreted as atypical or reactive endocervical cells. When atypical glandular cells are found, colposcopy with endocervical sampling is recommended.”

There are multiple reasons for this significant drop in gynecologic cytology claims:

- The change in technology from Pap smears to liquid-based testing, the use of algorithms for reflex testing for high-risk HPV, and following the Consensus Guidelines for managing women with abnormal cervical cancer screening tests.
- Pathologists are practicing in larger groups with workloads that justify adding a pathologist with subspecialty training in cytopathology.
- The implementation of Clinical Laboratory Improvement Act Proficiency Testing may have encouraged pathologists to close small cytology laboratories, thereby contributing to the growth of larger cytology laboratories that can afford the liquid-based technology and justify the addition of a cytopathologist to the practice.
- For over 15 years, there has been a rich pathology literature focused upon the following: the causes of false-negative cervical cytology tests; implementation

of quality assurance protocols and programs; innumerable CME programs on gynecologic cytology sponsored by national and state pathology societies; standardization of diagnostic terminology; and increased regulatory oversight. Pathology has done an exemplary job of “fixing the problem” of the 1980s and 1990s by addressing knowledge-based errors and, equally important, identifying and correcting system-based errors.

System errors changed from 1.3 claims per year from 1995 to 1997 to 3.7 claims per year from 1998 to 2003 to 2.1 claims per year from 2004 to 2010. Preanalytic errors included specimen mix ups with misassigned benign and malignant diagnoses (the great majority are breast and prostate needle biopsies); mislabeled specimens, biopsy sites, and slides; a lost needle biopsy; and a “floater.” Postanalytic errors included a transcription error and reports or diagnoses allegedly not called to the attention of or received by the clinician. It is my impression that this allegation is increasing, and my speculation is that it may increase still more as we transition to the electronic health record. It is important to document and date all phone calls or contacts with clinicians in the pathology report, the medical record, or both.

Claims involving misdiagnosis of cystic well-differentiated squamous carcinoma metastatic to a cervical lymph node as a branchial cleft cyst (BCC) continue at roughly the same frequency. Regardless of the patient’s age (they are often in an age group where cancer is not an initial consideration) or clinical diagnosis (often it is BCC), pathologists should be cautious about making a diagnosis of BCC when the cyst is lined by squamous epithelium. Metastatic squamous carcinoma should always be in the differential diagnosis, and the clinician should be advised to rule out a primary carcinoma in the mouth and upper respiratory tract whenever there is squamous atypia.⁸

Between 1995 and 2003, prostate needle biopsies accounted for 2.9% of all closed claims. These claims have decreased from 3 claims per year from 1995 to 1997 to 1.5 claims per year from 1998 to 2003 to no claims from 2004 to 2010, which is remarkable considering the number of prostate needle biopsies in most pathology practices. Between 1998 and 2003, the false-negative diagnosis of bladder intraurothelial neoplasia (carcinoma in situ) accounted for 1.5% of all claims. There were no claims involving bladder carcinoma in situ between 2004 and 2010.

Claims involving the misdiagnosis of sarcoma have decreased from 2.5 claims per year from 1998 to 2003 to 0.7 claims per year from 2004 to 2010. One of the 5 claims involved a false-negative misdiagnosis of synovial sarcoma, and 2 involved false-negative misdiagnoses of uterine sarcomas. In the 1998 to 2003 claims review, one third of sarcoma claims involved the false-negative diagnosis of synovial sarcoma.

Two of 7 claims involving colon specimens resulted from the misinterpretation of margins in Hirschsprung disease; 1 was for missing a lymph node micrometastasis in a resection for adenocarcinoma, and 1 was for

understaging an adenocarcinoma in the pathology report.

In the miscellaneous surgical pathology category, 1 claim was for failure to diagnose high-grade dysplasia in a biopsy showing Barrett metaplasia; the patient subsequently developed esophageal adenocarcinoma. One claim was for failure to identify brain tissue admixed with sinus contents, thereby not identifying that a surgical perforation of the sinus and cribriform plate had occurred.

Claims are frequently won or lost on the basis of the quality of the medical record. The pathology report should document the rationale for critical decision making. An incorrect diagnosis is easier to defend when the report reflects the thinking of a thoughtful and well-informed pathologist. In addition, claims are typically litigated 3 to 5 years after an event has occurred, and it is difficult to remember the case without a detailed report to review. Consider the following recommendations when writing the pathology report:

- Define pathology terms (atypical duct hyperplasia, atypical lobular hyperplasia, ductal carcinoma in situ, lobular carcinoma in situ, dysplasia, in situ carcinoma) in the report. Many medical schools have eliminated a formal course in pathology, and recent graduates may be unfamiliar with pathology nomenclature.
- For difficult diagnostic problems, discuss your differential diagnosis in the report. This may alert the clinician to provide clinically relevant information unknown to you, leading to a different diagnosis.
- Document recommendations for “additional diagnostic tests,” “follow-up studies,” or “treatment:” for example, recommending conservative reexcision when an “atypical melanocytic proliferation” extends to the margins.
- Issue written reports documenting verbal consultations. When you review a slide and offer an opinion, you are giving a consultation for which you can be held liable.
- The clinical information provided on the request slip should always be entered into the “clinical diagnosis” or “preoperative diagnosis” section of the report. When no clinical information is provided, this should be documented.
- When issuing a report before the results of special studies or expert second opinions are received, identify the diagnosis as a provisional diagnosis and state that a definitive or final diagnosis will follow.
- Issue a supplemental report when important new information is received subsequent to the release of the initial report.
- Document intradepartmental “second opinions” on malignant or suspicious diagnoses, diagnostic problems (melanoma), and uncommon lesions (bone and soft tissue tumors).

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