



Medical Malpractice Litigation: Head and Neck Cancer

Despite remarkable advances in scientific knowledge, medicine remains more art than science. As our understanding increases, the complexity of biologic systems is revealed to be ever greater.

Sophisticated new treatments are developed to harness the therapeutic implications of this knowledge, and patient expectations rise still more.

We have made manifest progress in lengthening the average lifespan, in treating certain forms of cancer, in reducing the ravages of stroke and coronary artery disease, and in surgical technique and reconstructive potential. Nonetheless, most medical progress is incremental, and outcomes are still not predictable for individual patients. Thus, the tide of litigation against America's doctors has risen even faster than medical progress.

Approximately one of every six practicing physicians faces a malpractice claim every year. In high-risk specialties such as obstetrics, orthopedics, trauma surgery and neurosurgery, there is one claim for each doctor every 2 1/2 years. In otolaryngology, the frequency of malpractice claims is .153. This means that approximately 15 percent of otolaryngologists report a claim every year. Therefore, the average otolaryngologist reports about one malpractice claim every six years. Seventy to 80 percent of all cases are found to be without merit. Nonetheless, each one requires a costly legal defense. Nationally, these litigation expenses averaged \$22,967 per defendant in 1999. Cases that go all the way through trial before a defense verdict cost an average of \$85,718 per defendant. A single national physician-owned insurer, The Doctors' Company, has spent more than \$400 million in legal fees defending claims that ultimately were shown to be without merit.

Coupled with this very high level of frequency, there has been a dramatic increase in severity. Severity is defined as the cost of the average claim, but by extension refers to the range of potential verdicts. The median cost of the average jury verdict in malpractice claims doubled to over \$1 million between 1997 and 2000. The average medical malpractice jury verdict exceeded \$3 million in 2002. Approximately eight percent of all malpractice claims now involve indemnities of \$1 million or more.

The range of outlier claims has increased even more. In 2000, Texas recorded a \$268 million malpractice verdict, and a number of states have experienced verdicts in excess of \$100 million. Though the threat of an appeal forces plaintiffs' attorneys to settle some of these larger awards for less than the amount of the full jury verdict, these judgments set the bar for settlement negotiations in cases where liability is present. Moreover, physicians feel increased pressure to settle even claims with doubtful liability when the potential damages could exceed their insurance coverage.

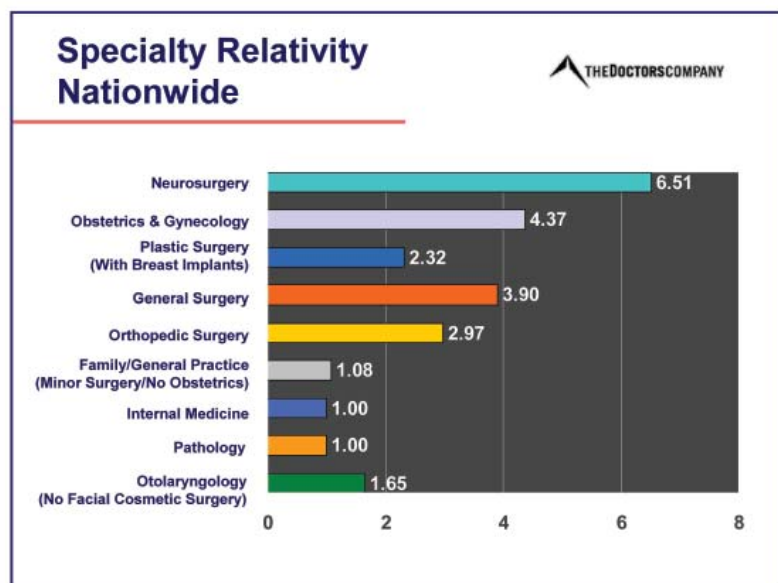
The product of frequency and severity can be used to create an index of specialty relativity. If we arbitrarily set internal medicine as 1.0, then neurosurgery has a relativity of 6.5. This means, in an actuarial model, the

average neurosurgeon would pay a malpractice insurance premium 6.5 times that of the average internist. For otolaryngology, excluding facial cosmetic surgery, the figure is 1.65. (See chart below.)

Historical antecedents

Medical liability claims were fairly uncommon until the 1970s when the first antecedent of today's crises occurred. Nearly 80 percent of California's malpractice claims for the first 75 years of the century were filed between 1970 and 1975. This unexpected litigation tide led most commercial insurance companies to conclude that the practice of medicine was uninsurable, and they refused to provide malpractice coverage at any price. This resulted in skyrocketing insurance rates, but moreover in a "crisis of availability" that left many physicians unable to find coverage at any price. The medical community responded emergently. Doctors contributed their own funds as capital to support the efforts of their state medical and hospital associations, among others, to start as many as 100 provider-owned specialty carriers across the country. These mutual or reciprocal insurers, owned by the policyholders themselves, today insure more than 60 percent of American physicians.

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The creation of physician-owned insurers was the product of necessity, but became feasible only after the passage of seminal tort reforms in California.

The second wave of litigation

A second crisis emerged in the early 1980s, again brought on by sharp increases in both frequency and severity. States like California and Nebraska, having passed necessary reforms a decade earlier, experienced no crisis. States that had failed to pass effective tort reforms experienced significant increases in the volume and cost of litigation. By this time the physician-owned insurers, as well as the returning commercial carriers, had adapted sufficiently to the medical-legal environment to continue to offer coverage, albeit with sharp increases in premiums. This crisis was primarily about affordability rather than availability. The system was able to accommodate this increase in litigation because physicians and hospitals were able to pass on at least some of the cost of these premium escalations in the fees charged to patients.

Cancer litigation

Allegations of malpractice involving cancer are probably the most common category of litigation in the United States. Of these, the majority involve putative delays in diagnosis. There are a number of reasons for this.

- Cancer is a common disease that will affect one in every four Americans. Fifty to 60 percent of these cases will be fatal, so the consequences of delay may be serious.
- Few diagnoses evoke the kind of visceral fear that cancer does. Frightened patients may focus on the medical process rather than the cancer itself as the offending entity.
- The public has been educated to place a very high value on early detection, so it is easy to believe that any delay in diagnosis can have dire consequences.
- It is often patients themselves who detect the index sign or symptom, so they are particularly aware of delays in properly addressing the problem.

Diagnosing cancer

Most cancers are readily detectable once the physician is determined to make a definitive diagnosis. However, the presenting signs and symptoms are often protean and suggest a broad differential diagnosis that includes many conditions encountered in daily clinical practice. To avoid missing cases, physicians must maintain a high index of suspicion, and exclude malignant disease with certainty. For example, every otolaryngologist encounters the following:

- Fever
- Night sweats

- Pruritis
- Pain
- Cough
- Hoarseness
- Lymphadenopathy
- Laboratory abnormalities in the complete blood count, serum alkaline phosphatase, lactic dehydrogenase, calcium, and sedimentation rate.

The differential diagnosis is broad and delays in diagnosis may occur for a number of reasons.

Routine assumption of benign etiology—For example, it is easy to attribute hoarseness or cough to an upper respiratory tract infection.

Acceptance of a sign or symptom as a diagnosis—For example, it is common to make a diagnosis of anemia without defining the etiology. This is, at best, an incomplete diagnosis. Even iron-deficiency anemia, which is a diagnosis, is incomplete unless the source of the iron deficit is identified.

Overreliance on indirect means of diagnosis—This potentially serious error may occur when physicians accept radiographic studies as definitive. A negative x-ray often does not definitively exclude cancer and an abnormal x-ray alone is usually insufficient to confirm a new diagnosis of cancer. All new diagnoses of malignant disease should be confirmed histologically where possible.

Failure to mandate adequate follow-up—It is important that patients with indeterminate findings be followed until a definitive diagnosis can be made. Physicians must be diligent in insisting on necessary evaluation. Because the physician is assumed to have superior knowledge, courts may not exonerate a doctor for a delayed diagnosis when the patient fails to appear for appointments. It may be necessary to prove the patient understood the potential implications of the behavior and the physician has made a reasonable effort to see that necessary evaluation is undertaken. This begins with ascertaining that tests ordered have actually been completed. In many cases a follow-up visit for a repeat examination of a borderline physical finding or repeat discussion of symptoms will be the difference between making a diagnosis and missing it.

Failure to review laboratory and x-ray reports—This oversight can be fatal. A regrettably common example is failure to act on a chest x-ray reporting a new coin lesion. In some cases, the report is filed in the patient's chart before being initialed by the physician. In others, the finding is not immediately communicated to the patient and is forgotten until the disease is advanced.



Malpractice Litigation in Otolaryngology

The risk profile of otolaryngology is an intermediate one, compared to other specialties. As a surgical subspecialty, it is not surprising that the majority of claims arise in the operating room, but delays in diagnosis make up the preponderance of the remaining litigation. A review of 100 consecutive closed claims in otolaryngology was undertaken at The Doctors Company, a national physician-owned malpractice insurer that covers 360 otolaryngologists².

The claims occurred between 1995 and 2002. Indemnity was paid in 25 percent of the cases, meaning the plaintiff received nothing 75 percent of the time. This approximates the company experience for all claims. Indemnities ranged from \$4500 to \$900,000. Of these, eight were \$100,000 or higher, with two above \$500,000. The average paid claim was just over \$150,000, compared to \$173,000 for the average paid claim company-wide. It is of interest that there were no indemnities in excess of \$1,000,000. Nationally, approximately 8 percent of all paid claims today exceed that figure.¹

Although the series of 100 paid claims for otolaryngology is the largest one available, we should not over-generalize from this sample. It was accrued over seven years, a period in which severity was increasing at an especially high rate in the latest years and may underestimate the cost of today's liabilities. Nonetheless, this data is consistent with the intermediate position of ENT along the medical liability spectrum.

Looking more closely at the claims themselves, 50 percent were operative complications of non-cosmetic surgery. An additional 29 percent represented alleged poor outcomes of cosmetic surgery. 12 percent involved delays in diagnosis. Of these 12 cases, 5 involved delays in the diagnosis of cancer, 3 of which resulted in death. Of the 100 claims overall, 9 involved the death of the patient.

Of the non-cosmetic surgery operative complications, there were 9 involving tonsillectomy, 9 involving septoplasty, and 9 involving sinus surgery. Interestingly, none involved laryngectomy or radical neck dissection and only two involved parotidectomy. There is thus a suggestion that head and neck cancer surgery actually presents a lower risk profile than more common procedures in the specialty, though proof would require a careful correlation with the volumes of each procedure. This would be consistent with risk assessment in specialties like medical or radiation oncology.

Patients are generally well aware of the serious nature of their disease, informed consent is undertaken more rigorously because of the potentially damaging consequences of therapy, and because perfect outcomes are not to be expected. Cancer specialists are also generally spared the litigation that surrounds the diagnostic process, since the cancer is at least overtly suspected prior to referral.

In this context, it is notable that 5 of 12 cases (42 percent) of delayed diagnosis involved cancer. This is consistent with the fact that the patient is usually aware of the index signs and symptoms of cancer of the head and neck, prominently including hoarseness or a neck mass, and thus is cognizant of delays in diagnosis.

Longitudinal reviews of jury verdicts involving cancer of the oral cavity⁸ and larynx⁹ have been undertaken. Lydiatt found 50 recorded cases involving cancer of the oral cavity between 1984 and 2000. The average age of the plaintiffs, forty-seven, was several decades younger than the age of peak incidence for the disease. Younger plaintiffs more frequently alleged misdiagnosis, won a higher percentage of their suits (60 percent) and received higher average awards (\$755,824) than the older cohort. 86 percent of the cases alleged delay in diagnosis. When the delay was three months or less, the defense won 86 percent of the time. This figure fell to 40 percent for longer delays.

For cancer of the larynx, the picture was generally similar.⁹ Twenty-three recorded jury verdicts involving this disease were found between 1976 and 1997. Eighty-three percent involved delay in diagnosis. Hoarseness was present in 53 percent, and 16 percent had a mass in the neck. Indemnity was paid just over half the time and was more likely in younger patients. General practitioners were the target defendants in about half of these cases.

Both these series are consistent with the observation that most cancer litigation revolves around the diagnostic, rather than the treatment, process. Schuring found that 20 percent of all suits against otologists are for failure to diagnose cancer.¹⁰

Assessment

Litigation involving head and neck cancer appears to be relatively uncommon, especially considering the extent of surgical intervention sometimes necessary for treatment. Some of the reasons for this have already been discussed. It is clear that delays in diagnosis are more likely to result in litigation, especially in the patient who presents for evaluation of a specific cancer-related complaint.

Most otolaryngologists are quite familiar with diagnostic paradigms for the specialty. Moreover, the diagnostic tools are usually in the hands of the doctor and do not rely on additional outside consultation. This makes the physician's liability relatively clear when the diagnostic process fails, but at least the necessary tools to complete the diagnosis are within the otolaryngologist's armamentarium.

Although contemporary reviews have detected few claims involving informed consent for cancer surgery, the allegation is common in other areas of otolaryngology, especially for elective or cosmetic surgery. In the future, however, we may anticipate more litigation alleging loss of opportunity for voice preservation when laryngectomy is recommended without discussion of organ-sparing

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alternatives, or when delays in diagnosis make laryngectomy the only appropriate therapy. This type of litigation has already appeared in breast cancer cases where allegations involving lost opportunity for breast conservation are increasingly common.

Overall, there can be no doubt that the tide of litigation is increasing. This means more lawsuits over issues rarely previously litigated such as lost opportunity for organ preservation and adverse outcomes involving even the most complex cases. In addition, there is more litigation in areas already heavily contested, such as delayed diagnosis cases alleging ever-shorter periods of delay.

Risk Management

There are no certain pathways to preventing litigation, in part because a significant percentage of the litigation is without merit. The notion that malpractice suits are directed only at “bad” doctors is not supported. In high-risk specialties such as neurosurgery, virtually all practitioners have already been sued, and on average half of neurosurgeons will report a malpractice claim every year.² The situation is not much better in a number of other specialties including obstetrics, orthopedics, and emergency medicine.

The authors of the *Harvard Medical Practice Study* could find no correlation whatever between the outcome of a malpractice lawsuit and the presence or absence of medical negligence. The only variable that correlated with suit outcome was the degree of injury. Patients with severe injury, regardless of cause, are more likely to be indemnified.¹¹ In addition, we know that 70-80 percent of all malpractice claims are closed with no indemnity payment.^{1,2}

Nonetheless, there are a number of things that can be done to reduce the likelihood of suit. The most obvious is maintaining excellent communication with patients. This goes beyond good bedside manner, though that is still important, to careful informed consent, thorough family discussions, and careful ascertainment of test results and follow-up responsibilities.

Maintaining excellent medical records is at least equally important. Most attorneys will argue that if it isn't written down, it didn't happen. Illegible records are not only problematic in court; they are also likely to be too brief for an adequate medical defense. Typed records are clearly preferable, but the next major step forward will be the electronic medical record. It has the potential to reduce common causes of malpractice litigation including laboratory and x-rays that have not been completed or reviewed, missed follow-up appointments, incomplete visit reports, and overlooked drug allergies. In the absence of national standard for such records, and the high cost of adopting currently available alternatives, it will be some time before such a system is widely available, however.

Lydiatt has drawn from experience in delayed diagnosis of breast cancer to offer the following guidelines for the evaluation of oral cancer⁸:

- Patients' statements that something is different must be heeded.
- A firm diagnosis must be made for any abnormality, or the patient must have referral or follow-up.
- Cancer must be considered in all patients with symptoms, irrespective of age.
- Patients with neck masses must be followed to resolution or diagnosis.
- All follow-up should be directed so that definitive diagnosis is made within three months.
- Patients, dentists, and physicians must understand that repeated examinations may be necessary to arrive at a diagnosis.
- Fine-needle aspiration, tissue biopsy, or radiographic examinations cannot be considered definitive if they are inconsistent with the clinical examination.
- Biopsy of any suspect lesion should be performed.
- A complete history must be taken.
- Maintain close communication with the patient's other healthcare providers.
- Primary care physicians and dentists must screen for oral cancer.

It is important to avoid disparaging remarks about prior care. It is all too easy to make even unintentionally negative comments about aspects of a patient's history, or the interpretation of equivocal studies, or the appearance of a scar, or how one might have approached a problem differently. The problem here is the absence of firsthand knowledge of the circumstances. Perhaps something might have been done differently, but not being there at the time makes it difficult to know with certainty. Caution in this area does not mean hiding obvious error, or ceasing to be the patient's advocate. It does mean maintaining appropriate rigor in judgments based on incomplete evidence.

Direct doctor-to-doctor communication can be equally problematic. It is critical that referring physicians forward complete medical records to consultants, and that consultants in turn report their findings back in detail. Too often physicians work in parallel rather than intersecting tracks, leading to uncoordinated care at best, and missed diagnoses at worst. Detailed communication is also necessary in on-call handoffs. Too often we rely simply on faith in our colleagues without providing information necessary to make critical decisions.

Doctor-to-patient conversations should be clear and well documented. This is especially important for phone calls, where often no record at all exists, and a court is left to choose between conflicting accounts from doctor and patient. Handling necessary follow-up presents a similar problem. The recommendation should be clear, and



documented, and an effort made to contact the noncompliant patient. While this may seem an unfair burden on the physician in this era of patient autonomy, the effort is well rewarded when it results in improved outcomes and prevents an undeserved lawsuit.

Finally, many otolaryngologists will follow patients long-term for specific specialty-related problems. Examples range from cancer follow-up to chronic sinusitis. Often patients will come to rely on these regular encounters for all their medical care, and neglect primary care physicians and general prevention and screening. While there should be no expectation that mammograms and prostate examinations will be done by otolaryngologists, it is an extremely good idea for the specialist to remind the patient that other aspects of care continue to require attention, even when concern is primarily focused on serious problems such as malignancy and its ramifications.

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