

Head and neck, oral, and oropharyngeal cancer: a review of medicolegal cases



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Objective. The purpose was to review cases of malpractice in head and neck cancer (HNC) in order to examine allegations and outcomes of the litigation and to assess the implications for best practices in the clinical care of patients with HNC.

Materials and Methods. Three U.S. legal databases were accessed to assess the basis of the cases and the outcomes reported.

Results. Dental and medical health care providers are identified in cases with alleged failure to diagnose or delayed diagnosis. In addition, inadequate prevention and management of oral complications of cancer therapy also may result in medicolegal action. In the dental cases, the mean recovery was \$1,033,500.11, and in medical cases, it was \$2,828,639.20.

Conclusions. In addition to failure in the diagnosis of malignant disease, our review identified failure to properly prevent and manage oral complications as potential causes of medicolegal actions. Evidence-based care with a multidisciplinary team may promote diagnosis of disease and prevention and management of complications. (Oral Surg Oral Med Oral Pathol Oral Radiol 2015;119:177-186)

Cancers in the head and neck region at early stages are commonly associated with few symptoms, and when symptoms are present, they may be minor and nonspecific. Even advanced-stage cancers at initial presentation may have few, minimal, or nonspecific symptoms. Mucosal lesions may appear clinically innocuous, presenting as red or white changes that may mimic benign conditions and may not raise concerns in the patient or the examiner. Establishment of a diagnosis is a process that requires the synthesis of a series of events and observations ultimately including the patient's presentation in a health care environment. Diagnosis can be completed following a comprehensive patient history, thorough examination of the head and neck and oral tissues, knowledge of variations of normal, and an index of suspicion for findings that could represent oral potentially malignant epithelial lesions (PMEL), squamous cell carcinoma (SCC), or other neoplasms, including those of salivary and lymphoid origins, among others. Diagnosis requires recognition of the abnormal, as well as appropriate and accurate testing and interpretation of results. Upon diagnosis, referral for appropriate cancer therapy and

prevention of common oral and other local complications of treatment following current standards of care are necessary.

The diagnostic process presents the risk for delay or misdiagnosis at each step from patient presentation to tissue diagnosis. In cases of oral squamous cell carcinoma and oropharyngeal squamous cell carcinoma, delays in diagnosis of more than 1 month have been reported to contribute to diagnosis of later-stages of disease.¹⁻³ However, other studies have not shown statistically significant associations between the stage of disease and delay and the outcomes of therapy.^{4,5}

A study evaluating time to treatment reported a mean delay of referrals to specialists of 5.1 weeks and a mean time to surgical treatment of 5.2 weeks and 10.3 weeks for radiation therapy. However, patient delay from first symptom to diagnosis may be the cause of longest delay; one study reported a mean delay of 4.9 months.⁶

Dentists may identify early symptoms or signs of PMEL and head and neck cancer (HNC) more commonly compared with physicians (72.5 % dentists, physicians 40%).^{7,8} However, a study of dentists and physicians found that only 58% of dentists reported routinely examining patients for oral cancer, and physicians reported examining the mouth only when

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Statement of Clinical Relevance

Medicolegal actions may occur due to alleged delay or failure in diagnosis and with alleged failure to prevent and manage oral complications of cancer therapy and may involve dentists and/or physicians. Following current guidelines for the detection and diagnosis of cancer and for the management of oral complications may reduce the risk.

Table I. Summary of dental malpractice cases

<i>Incident date</i>	<i>Filing date</i>	<i>Mediation/ trial date</i>	<i>Primary diagnosis</i>	<i>Malpractice liability</i>	<i>Allegations</i>	<i>Outcome of case (value in 2012 dollars)</i>
Apr-03	Dec-05	Settlement: Sep-06	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Mediation \$50,000 (\$57,370)
N/A	Oct-87	Settlement: Jan-88	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	\$200,000 (\$391,068)
N/A	N/A	Trial: May-84	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	\$3,500,000 (\$7,792,199)
Jul-93	N/A	Trial: Dec-97	Oral cancer	Diagnosis	Failure to diagnose; lesion attributed to inflammation	Defense prevailed (\$0)
Oct-85	N/A	Trial: Sep-90	Oral cancer	Diagnosis	Failure to diagnose oral cancer from X-rays	Defense prevailed Past Medical: \$4000 (\$7,079)
Oct-02	N/A	Trial: May-06	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	\$1,199,999 (\$376,886)
Aug-98	N/A	Trial: Apr-02	Oral cancer	Diagnosis	Failure to diagnose, progression of disease	\$870,000 (\$1,1168,663)
Jan-94	Oct-97	Settlement: Apr-98	Oral cancer	Diagnosis	Failure to diagnose; progression of disease; facial disfigurement Defendant: Cancer already advanced; patient negligence	Settlement: \$1,000,000 (\$1,419,123)
N/A	N/A	Trial: Mar-94	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Settlement: \$325,000 (\$507,724)
Mar-07	N/A	Settlement: Jan-10	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Settlement: \$500,000 (\$530,407)
Mar-93	N/A	Trial: Oct-98	Oral cancer	Diagnosis	Failure to diagnose; progression of disease; clinician and pathologist	Settlement: \$300,000 (\$425,737)
Sep-86	N/A	Trial: Jan-89	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	\$1,098,054 (\$2,048,375)
Jun-05	N/A	Settlement: Apr-07	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Settlement: \$180,000 (\$200,813)
Feb-88	N/A	Trial: Nov-92	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Settlement: \$220,000 (\$362,721)
Dec-88	N/A	Trial: May-91	Oral cancer	Diagnosis	Failure to diagnose; pathologist and oral surgeon	\$1,300,000 (\$2,207,871)
2005	N/A	Trial: Jan-10	Oral cancer	Diagnosis	Failure to diagnose; progression of disease Failure to refer for biopsy	Settlement: \$500,000 (\$528,030)
May-06	N/A	Trial: 2009	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Jury award: \$150,000,750 State's malpractice reduced to \$619,000 Total recovery \$525,000 (\$563,525)
Jan-04	N/A	Settlement: Apr-07	Oral cancer	Diagnosis	Failure to diagnose persisting lesion	Settlement: \$180,000 (\$199,913)
Apr-02	N/A	Settlement: Jun-05	Oral cancer	Diagnosis	Failure to diagnose; failure to submit excised tissue for pathology	Settlement: \$400,000 (\$471,644)
Aug-98	N/A	Trial: Apr-03	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Defense prevailed (\$0)
N/A	N/A	Trial: Nov-99	Oral cancer	Diagnosis	Failure to diagnose; more extensive surgery and radiation with damage to salivary glands	Defense prevailed (\$0)
Dec-92	N/A	Trial: Apr-98	Oral cancer	Diagnosis	Failure to diagnose; progression of disease.	Defense prevailed (\$0)
Jul-92	N/A	Trial: Jan-98	Oral cancer	Diagnosis	Failure to diagnose; progression of disease Defendant claimed biopsy recommended; patient refused	Defense prevailed (\$0)
Jul-93	N/A	Trial Dec-97	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Defense prevailed (\$0)
Dec-86	N/A	Trial: Jun-92	Oral cancer	Diagnosis	Failure to diagnose progression of disease Defendant's initial lesion diagnosed as abscess was not associated with cancer	Defense prevailed (\$0)

Table I. Continued

<i>Incident date</i>	<i>Filing date</i>	<i>Mediation/ trial date</i>	<i>Primary diagnosis</i>	<i>Malpractice liability</i>	<i>Allegations</i>	<i>Outcome of case (value in 2012 dollars)</i>
N/A	N/A	Trial: Dec-11	Osteonecrosis	Diagnosis	Delay in diagnosis of osteonecrosis Defense claimed that standard of care was maintained and earlier diagnosis did not affect outcome	Defendant prevailed (\$0)
Feb-08	N/A	Settlement: Apr-12	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Settlement: \$800,000 (\$800,000)
Dec-03	N/A	Trial: Mar-11	Oral cancer	Diagnosis	Failure to diagnose oral cancer and progression of disease, leading to death	Defense prevailed (\$0)
Jun-02	N/A	Trial: May-06	Oral cancer	Diagnosis	Failure to diagnose; progression of disease	Defense prevailed (\$0)
May-92	Jan-94	Trial: Jul-96	Osteoradionecrosis	Informed consent	Failure to inform osteonecrosis risk with prior radiation and treatment options	Plaintiff: 49% negligent, \$1,454,319 (\$2,144,096)
May-92	N/A	Trial: Jul-96	Osteoradionecrosis	Informed consent	Failure to inform of risk of necrosis; failure to refer for hyperbaric oxygen	\$1,018,000 [51% defendant fault; 49% plaintiff's] (\$1,300,833)
Dec-04	N/A	Trial: May-11	Osteonecrosis	Informed consent	Failure to disclose risk of osteonecrosis associated with zoledronic acid before extraction Defense claimed that labels provided adequate explanation of risk	Defendant prevailed (\$0)
Jun-03	N/A	Trial: Apr-07	Oral cancer	Informed consent; treatment	Failure to inform of alternative procedures and risk of trismus Failure to obtain clear margins	Defense prevailed (\$0)
Feb-05	N/A	Trial: Jun-09	Osteoma	Informed consent; Treatment	Inappropriate surgery; lack of informed consent Defense claimed risk of necrosis with bisphosphonate not well known at the time of the surgery	Defendant prevailed (\$0)
Dec-01	N/A	Trial: Dec-04	Salivary gland excision	Informed consent, treatment	Failure to inform risk chronic dry mouth with of salivary gland excision	\$596,323 (\$732,906)
Jan-04	N/A	Trial: Oct-90	Oral cancer	Treatment	Negligent removal of tumor; metastasis, leading to more extensive surgery	\$833,000 (\$1,474,269)
Jan-85	Jan-87	Trial: Mar-94	Osteoradionecrosis	Treatment	Failure to diagnose osteoradionecrosis before tooth extraction	\$2,960,000 (\$4,620,097)
Oct-85	N/A	Trial: Sep-94	Osteoradionecrosis	Treatment; dentist and hospital	Failure to extract before radiation therapy; extraction following necrosis; lack of informed consent; failure to refer	Total \$2,900,000 (70% general dentist; 25% hospital dental center)
Jun-85	N/A	Settlement: 1989	Osteoradionecrosis	Treatment	Failure to take precautions in extraction following radiation therapy	Settlement: \$1,001,308 (\$1,867,900)
1985	N/A	Trial: Mar-94	Osteoradionecrosis	Treatment	Extraction of teeth despite knowledge of prior radiation treatment	\$2,960,000 (\$4,620,097)
Apr-97	N/A	Jan-00	Osteonecrosis, extraction	Treatment	Incomplete health history; not aware of radiation for Hodgkin disease Osteoradionecrosis, mandibular fracture, septicemia, brain damage, visual loss following extraction	Hearing pending (\$0)

N/A, not available.

Table II. Summary of medical malpractice cases

<i>Incident date</i>	<i>Filing date</i>	<i>Mediation/ trial date</i>	<i>Primary diagnosis</i>	<i>Malpractice liability</i>	<i>Allegations</i>	<i>Outcome of case (in 2012 dollars)</i>
N/A	N/A	Settlement: Jan-91	Cancer: jaw	Diagnosis	Failure to diagnose lump in jaw with history of lip cancer	Settlement: \$225,000 (\$382,130)
Jul-09	N/A	Trial: May-12	Cancer: oral	Diagnosis: Physician and hospital	Failure to diagnose leukoplakia; progression to cancer with metastasis Defendant: patient noncompliant	Fault: 40% plaintiff, 0% doctor, 40% hospital: \$368,500 (\$368,500)
Jan-82	Jan-85	Trial: May-90	Cancer: jaw	Diagnosis	Failure to diagnose mass in jaw, altered medical records Defendant: patient failed to return for follow-up; did not alter records	\$505,000 (893,765)
N/A	N/A	Trial: Jun-91	Cancer: oral	Diagnosis	Failure to diagnose; progression of disease	\$1,200,000 (\$2,034,035)
Mar-97	Jan-99	Trial: Jun-01	Cancer: oral	Diagnosis	Failure to diagnose; progression of disease; unnecessary radiation; more extensive surgery	\$2,617,000 (\$3,418,163)
Oct-87	Jan-91	Trial: Feb-92	Cancer: oral	Diagnosis	Failure to diagnose metastatic melanoma	\$1,200,000 (\$1,978,478)
Feb-00	Oct-03	Trial: Jun-07	Cancer: oral	Diagnosis	Failure to diagnose oral complications, progression of disease; extensive surgery, permanent feeding tube	\$6,400,000 (\$7,140,033)
N/A	N/A	Settlement: Apr-92	Permanent damage to salivary glands	Diagnosis	Misdiagnosis of melanoma as oral cancer, incorrect treatment	\$400,000 (\$659,493)
Sep-92	N/A	May-99	Cancer: oral	Diagnosis	Failure to stage and treat cancer	\$475,000 (\$659,517)
N/A	N/A	Oct-03	Cancer: oral; salivary gland damage	Diagnosis	Failure to diagnose; progression of disease; radiation damage to salivary glands	Defense prevailed (\$0)
Aug-97 to Oct-97	N/A	Mar-05	Cancer: Oral	Diagnosis	Failure to biopsy, delay in diagnosis. Defendant contended lesions due to a viral syndrome	Defense prevailed (\$0)
December 2002-April 2003	N/A	Oct-06	Cancer: oral	Diagnosis	Delay in diagnosis; more extensive treatment and associated toxicities Defense: performed a biopsy at initial presentation but results were negative	Defense prevailed (\$0)
Oct-85	N/A	Trial: Sep-90	Cancer: oral	Diagnosis	Failure to diagnose nodal metastasis	Defense prevailed (\$0) Past Medical expenses: \$4000 (\$7,079)
Jan-85	Feb-88	Trial: Mar-93	Cancer: oral	Prevention: Physician and hospital	Failure to prevent mucositis; dental damage	\$308,433 (\$382,132)
N/A	N/A	Verdict: Mar-02	Cancer: oral	Treatment	Treatment without cancer staging; radiation therapy without adequate healing of surgical flap; multiple facial and leg surgeries	\$1,902,178 (\$2,445,837)
Jan-00 -1977	Jul-01	Verdict: 2002	Cancer: oral and pharyngeal	Treatment	Failure to provide adequate postoperative care	\$12,887,000 (\$739,340)
	N/A	Verdict: Jul-93	Cancer: brain stem	Treatment	Radiation therapy to wrong side; hearing loss 7 years after treatment due to osteoradionecrosis	\$3,500,000 (\$5,602,834)

Table II. Continued

Incident date	Filing date	Mediation/ trial date	Primary diagnosis	Malpractice liability	Allegations	Outcome of case (in 2012 dollars)
Jan-01	2006	Nov-10	Cancer: oral, with lung and spinal metastasis	Treatment	Failure to refer for chemotherapy; metastasis to lung and spine	Defense prevailed (\$0)
N/A	N/A	Jan-07	Cancer: oral	Treatment	Failure to excise adequate margins during surgery; recurrence; extensive treatment and ultimately death	Defense prevailed (\$0)
Feb to Apr-05	N/A	Jun-09	Osteoma	Informed consent; treatment		Defense prevailed (\$0)
Jan-05		Nov-12	Breast cancer and osteonecrosis	Informed consent; treatment	Failure to recognize risk of osteonecrosis; breach of bisphosphonate implied warranty	\$10.45 million Personal injury: punitive exemplary damages (\$10,000,000) Personal injury: past pain and suffering (\$350,000) Personal injury: future pain and suffering (\$100,000)
Oct-04	N/A	Apr-12	Osteonecrosis	Informed consent; product liability	Failure to disclose risk of osteonecrosis; breach of bisphosphonate implied warranty	\$225,000 (\$227,521)

N/A, not available.

symptoms are reported.⁹ Self-report of confidence in detection of PMEL and HNC are poor in both dentists and physicians (dentists 37% vs physicians 15%).¹⁰ The examination must include cranial nerve examination, head and neck cervical lymph node examination, and inspection and palpation of oral soft tissue. However, only two-thirds of dentists report palpation of cervical lymph nodes always or usually, and intraoral palpation was reported in less than one-third of patients.⁸

Acute and chronic oral complications of cancer therapies have been reviewed recently.¹¹ National and international guidelines for the prevention and management of oral complications in cancer therapy have been developed and promulgated by the Multinational Association for Supportive Care in Cancer and the International Society for Oral Oncology and aspects of oral care supported by the American Society of Clinical Oncology and the European Society of Medical Oncology.¹² These guidelines are available from the National Information Clearing House of the National Institutes of Health and on the National Cancer Institutes of Health website.¹³ These sources provide guidance and standards for the prevention and management of complications and support the need for multidisciplinary care for patients and survivors of cancer. Acute oral complications include mucositis, pain, infection, dry mouth, taste alterations, dental complications, difficulty swallowing, and speech alterations. Extension of treatment-related complications and ultimate survivorship issues include pain, infection, dry mouth, bone and soft tissue necrosis, taste change, dental and periodontal disease, scarring and fibrosis and limitation of oral tissue, and restriction in jaw and head and neck movement. Thus, national standards have been developed for oral care and management throughout the treatment phase and beyond.

The purpose of this paper is to review the medico-legal actions summarized in three national legal databases related to HNC and their implications for patient care by dental and medical providers.

MATERIALS AND METHODS

We accessed three legal databases—LexisNexis,¹⁴ JVR Verdictfinder,¹⁵ and www.verdictsearch.com.¹⁶

The first legal database that was accessed was LexisNexis.¹⁴ This database was searched using the following search terms: “failure to diagnose and or treat oral cancer,” “osteoradionecrosis” and “biphosphonate necrosis.” These search terms initially generated 110 results, and these results were screened to eliminate non—oral cancer cases and defense verdicts. This resulted in a total of 13 cases that included either settlements or plaintiff verdicts.

In searches of subsequent databases, we used the same terms; however, when use of prior search terms did not return cases, we added additional terms in order to identify cases in the database based on the search terms appropriate for the specific database.

We then searched the legal database JVR Verdict-finder.¹⁵ This nationwide search covered the 10 years before the search date of November 15, 2012. Search terms for this database included “osteonecrosis,” “osteonecrosis,” “bisphosphonate osteonecrosis,” “pathologic fracture,” “severe rampant dental disease,” “xerostomia,” “chronic pain,” “death,” “failure to diagnose and treat oral cancer,” “delayed referral,” “failure to prevent osteonecrosis, osteonecrosis, bisphosphonate osteonecrosis, pathologic fracture, rampant (severe) dental disease,” “Oral/dental complications of cancer therapy: toxicity and oral complications of cancer therapy.” This resulted in the identification of 27 cases of settlements or plaintiff verdicts, six of which were eliminated because they were unrelated to the issues addressed in this study.

The third database searched was www.verdictsearch.com.¹⁶ Initially, a global search of the term “dental malpractice” was performed to determine the potential number of cases in the database on this topic. This yielded 291 total cases. The database was then searched by the following search terms, and the following numbers of cases were generated: “dental pathologic (0 cases),” “caries (5 cases),” “oral cancer (18 cases),” “osteonecrosis (1 case),” “xerostomia (1 case),” “rampant dental (6 cases)” and “osteonecrosis (32 cases).” In an attempt to isolate additional related cases from ones outside the scope of this article, the following search terms were used with the 291 dental malpractice cases: “cancer (12 cases),” “toxicity (0 cases)” and “dental caries (1 case).”

RESULTS

Forty-one malpractice cases found in the searches of the legal databases identified dental providers (Table I), and 23 identified medical providers (Table II). Outcomes resulting in zero payment to the plaintiffs were excluded from the financial analysis in this article but included for analyzing the nature of the allegations asserted.

Of the cases naming dental providers, 30 cases were related to alleged delay in diagnosis or misdiagnosis (Figure 1), 10 cases were related to oral complications, most commonly due to osteonecrosis, 6 due to issues related to informed consent, and 5 due to negligent treatment. (Note: Some of the 41 cases alleged more than one cause). Eight cases were found in favor of the defendant. Of the cases where the plaintiff obtained a recovery, the highest amount recovered was

\$3,500,000.00. The mean recovery of the 26 cases, including verdicts and settlements, was \$1,033,500.11.

Of the cases naming medical providers (Figure 2), 16 cases were related to alleged delay in diagnosis or misdiagnosis, 5 to osteonecrosis, and 5 to negligent treatment errors. (Note: Some of the 22 cases described more than one alleged cause). Six cases were related to failure to prevent or effectively manage the oral complications of cancer treatment. Seven cases were in favor of the defendant. Of the cases where the plaintiff obtained a recovery, the highest amount recovered was \$12,887,000. The mean recovery of the 15 cases, including verdicts and settlements, was \$2,828,639.20.

The search of the legal databases for medical cases identified three cases related to the antecedent use of bisphosphonates and osteonecrosis. These results included the largest award listed above (\$12,887,000 awarded in a products liability action), as well as recoveries in the amount of \$10,450,000 and \$225,000.

DISCUSSION

Patient outcomes and the medicolegal implications of delayed or missed diagnosis of oral malignant disease are recognized, as they may result in large damage claims based on the cost of care, pain, suffering, potential disfigurement, lost income, negative impact on quality of life, and potential loss of life. Oral complications are of increasing importance in the care of patients with cancer¹¹ but have received less attention despite the medicolegal implications identified in this article. Legal issues are also impacted by the completeness and accuracy of the patient records, which may compound liability issues when the records are inadequate, incomplete, or altered.

Detection, leading to diagnosis, begins when an abnormality is recognized and differentiated from variations of normal. HNC may present with few, minimal, and nonspecific symptoms, and now increasingly with human papilloma virus—associated cancer, HNC may present with lymphadenopathy and occult primary disease. Patient delay may be due to no or minimal symptoms, and symptoms and signs must be sufficient for the patient and the health care provider to recognize an abnormality even when a coincidental finding is made in a routine follow-up visit. Similarly, minor and nonspecific symptoms may be overlooked or minimized by the health care worker. It is well known that the rate of progression from premalignant conditions to cancer is not predictable, and this may vary with the lower risk of cancer progression for PMEL with mild dysplasia or more advanced and severe cellular changes that may progress rapidly in some cases once the condition progresses to SCC. In addition, whether dysplasia of varying degrees of severity will progress or regress

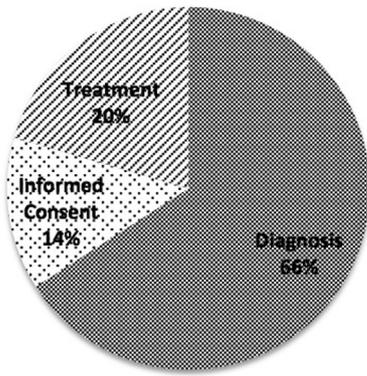


Fig. 1. Dental malpractice cases.

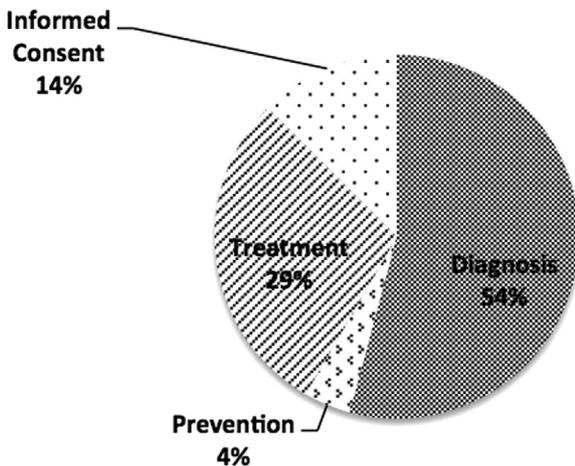


Fig. 2. Medical malpractice cases.

cannot be predicted. Cellular heterogeneity within and between tumors further complicates prediction of tumor behavior. In addition, the histologic diagnosis of various stages of premalignancy and cancer is at times subjective^{17,18} and, like clinical evaluation, requires the involvement of experienced providers and diagnosticians.

Recognition of signs and symptoms that may represent malignant disease in the head and neck are critical and may be the reason a patient presents to the health care worker. Variations of normal and fluctuating symptoms (e.g., mild sensitivity or discomfort) reduce the probability of a malignant condition, whereas persisting and progressive symptoms must be addressed. However, oral PMEL and early-stage SCC may often be asymptomatic or present with minimal and nonspecific symptoms. More advanced disease may be associated with symptoms, including discomfort, local numbness or tingling, limited movement of the involved tissue (e.g., lips, tongue, or soft palate), speech alterations, presence of a mass, an ulcerated lesion and/or bleeding from the involved site, sore throat, difficulty swallowing, and mass or swelling in the neck, and in

cases of advanced disease, weight loss may be noted. It should also be pointed out that sometimes the detection and diagnosis of HNC is difficult even in the presence of one or more of these signs and symptoms and even when the standard of care is met by the dental or medical professional.

Although, the literature is not clear on the time delay that may be of significance,¹⁻⁶ delayed diagnosis and progression in stage of disease is the most common allegation in HNC malpractice cases identified in the legal databases. Failure to diagnose or refer for diagnosis is a common factor in litigation.^{10,19-21} Failure to recognize past cancer therapy to the region of concern and the impact this may have upon dental treatment that may lead to complications also clearly represent potential for malpractice claims.

In a previous report, we identified example cases to provide guidance from prior cases of litigation related to HNC.²¹ The reasons are multifactorial and include limitation in training and inexperience in diagnosis of cancers, and because signs and symptoms may be nonspecific, minimal, or subtle and the low disease prevalence may result in a low index of suspicion.^{9,22} The changing epidemiology of HNC and oral cancer among younger people and the expansion of at-risk populations due to certain forms of human papilloma virus and immunosuppression are changing the presentation of disease and altering risk profiles.¹¹

Acute and chronic oral complications of disease and treatment that require prevention and management cross boundaries between dentistry and medicine. Oncologists must take action to limit or prevent oral complications when possible, which requires a close working relationship with informed and experienced dental providers and knowledge of guidelines for patient care that have been established. Failure to recognize this obligation is seen in a number of cases identified in this review of malpractice claims (Tables I and II; Figures 1 and 2). Prevention and management of oral complications is, however, affected by limited training and experience in oncology among dental providers, and similar limitation in the training and experience of medical providers with regard to oral and dental care. The treated patient with oral cancer and HNC becomes a more complex and potentially compromised dental patient. Oncologists should understand the specialized nature of the potential oral conditions and be aware that the training and experience of the dental professional may be limited and that this may be best managed by experienced dentists integrated into the oncology team.²³

To achieve an accurate diagnosis, clinicians must select the most appropriate diagnostic test(s), which must be conducted and interpreted appropriately. In the case of biopsy performance, site selection, technique,

and quality of the tissue specimen must be considered, as these may affect the pathologist's diagnosis. Furthermore, the interpretation of the biopsy specimen may also be affected by the level of experience and training of the pathologist. Interpretations of oral biopsies have shown interrater and intrarater variability in sign-out diagnoses.^{17,18} Tissue evaluation may require special tissue stains and techniques (e.g., flow cytometry, immunohistochemistry, molecular and genetic analysis, etc.), which may assist or be required to achieve tissue diagnosis. Additionally, the selection of diagnostic studies depends on the experience of the pathologist with regard to head and neck pathology and the range of testing options available to that person. In cases where the histopathologic diagnosis is not consistent with the clinical appearance or behavior of the lesion, review of the pathology, repeating the biopsy, use of special tissue stains, and/or obtaining other pathologist's opinions may be needed. Consideration should also be given to referral to more experienced health care providers in such cases. In addition, such conditions as proliferative verrucous leukoplakia present a challenge, as diagnosis is based on clinical findings supported by histologic findings; it cannot be confirmed on histopathology alone and therefore requires experience in the clinical diagnosis and management of oral mucosal disease.²⁴ Other tissue sampling techniques, including exfoliative cytology, fine-needle aspiration, and core biopsy, which involve cell collection and diagnostic interpretation, are also subject to variability in interpretation. Molecular techniques may add information to that obtained in tissue evaluation and increase the accuracy of the tissue diagnosis. Given the rapid advances in research and clinical care, seeking expert referral and newer molecular tests in diagnosis should be considered. Furthermore, additional diagnostic testing may include imaging (e.g., dental radiography, computed tomography, magnetic resonance imaging, positron emission tomography), which requires interpretation by radiologists and other health care providers and is subject to the limitations of the imaging modality chosen and the variability in the training and experience of the individual interpreting the images.

Delay in diagnosis and the resultant progression of disease are common allegations in malpractice cases related to HNC.^{21,25} In approximately half the legal cases found involving HNC, biopsies were allegedly indicated but not performed.²⁵ In 2001, the average cost of defending medical malpractice claims in the United States was \$28,801, and the median cost of jury awards was \$1 million in 2003.²⁶ In our review, the mean recovery where plaintiffs were successful was \$1,033,500.11 for dental cases and \$2,828,693.20 for the medical or products liability cases.

Lydiatt²⁰ reviewed jury outcomes for 50 cases involving HNC from 1984 to 2000 using the Westlaw (St. Paul, Minnesota) legal database. In this review, defendants won in 42% of cases, plaintiffs prevailed in 32%, and 26% of cases reached a settlement.²⁰ In our review of the legal databases, we focused on those cases where the plaintiffs obtained a recovery. The most common allegations were failure to diagnose, failure to perform a biopsy, failure to provide a referral, and complications associated with cancer treatment. In patients under 47 years of age, the average award was \$755,824, and in those older than 47 years, awards averaged \$495,417.²⁰ Of 26 cases that went to trial, 8 were won by the defendant, and those in favor of the plaintiff had a mean award of just over \$2,000,000. Those cases settled by mediation had a much lower mean award of approximately \$475,000.

Lower levels of awards were reported in 86% of the cases where alleged delay was less than 3 months and 40% where the alleged delay was more than 3 months.²⁰ As in other studies, common allegations were failure to perform a biopsy and failure to provide a referral.^{20,21,25,26} Forty-five percent of the 50 legal cases were found against dentists, and 60% of these cases alleged that the dentist did not have a biopsy performed.²⁰ In a study of cases involving antral and sinonasal cancers, similar findings were reported.²⁷ Defendants prevailed in 62% of cases, with a median award of \$650,000. Younger patients prevailed at a higher rate than did older patients (50% vs 35%), and men had a higher median award than did women (\$1 million vs \$314,000).²⁷

Health care providers must recognize an abnormality and take steps to achieve a definitive diagnosis or refer the patient to a more experienced or specialist dental or medical care provider in order to avoid medicolegal risk, even though the impact of delay in diagnosis and treatment is not well documented. The impact of delay is affected by the biologic variability of the tumor, host or individual factors, and referral bias. Nevertheless, from a legal perspective, a delay in diagnosing or referring a patient could be costly. The elements typically required in malpractice cases include showing a breach of the standard of care and that the injury or negative effect resulted from that deviation.^{20,21,27-29}

Although the facts of a case determine the outcome, intangible factors, including such issues as sympathy for the plaintiff or the family, may also be considered despite instructions given by courts to juries to disregard such feelings of sympathy from their consideration of the case.²⁵ However, it is important to note that a poor outcome in oncology is not necessarily evidence of malpractice, as outcomes are associated with individual findings, such as the stage of the disease or the biology of the tumor.

The medical malpractice environment may be reaching proportions that threaten the delivery of health care.²⁵ The most common allegation of malpractice claims in patients with HNC is delay in diagnosis. Often, plaintiffs are younger than those expected to be at risk. In addition to delays in diagnosis, allegations can also include increased morbidity and possibly poorer treatment outcomes.^{20,25}

Our review showed that lack of prevention, recognition, and management of oral complications following current national standards of care may lead to medicolegal action. In such cases, these were the factors that were the basis of 31% of cases involving oncologists and 29% of cases involving dental providers. These complications included mucositis, xerostomia (and related complications), and osteonecrosis of the jaw. These cases emphasize the need for prevention, early detection, and appropriate management best provided by functioning oncology teams that include experienced medical and dental providers.

Study limitations include practical limitations with regards to the availability of data, and therefore, the results are only reflective of the available data. Despite the vast resources used by the searched databases, many cases may not make their way into these databases. Court records are yet to be universally electronic or made available to these databases. Additionally, settlements are, more often than not, kept confidential. Therefore, there are likely a large number of cases not represented in the data considered by this article. These cases have the potential to significantly impact the values and percentages resulting from the data considered in our analysis.

CONCLUSIONS

The reported knowledge, training, and experience of dental and medical providers may impact the recognition, detection, and diagnosis of oral premalignant and malignant disease and in the recognition, prevention, and treatment of oral complications of cancer therapy. In addition, the separation of medicine and dentistry in the practical aspects of delivery of care, including in payment and reimbursement systems, increases the barriers in obtaining medically necessary oral care and also impacts research in multidisciplinary disease and treatment with broad impact on quality of life and cost of care. Undergraduate medical training, dental training, graduate and residency training and continuing education, and in-service care models are needed to overcome these challenges.^{19,27,30-32} Risk management goals for early detection to prevent delays in the diagnosis, prevention, and management of oral complications of cancer therapy may help prevent subsequent litigation. Health care providers must be diligent in maintaining an index of suspicion, developing a set of

differential or possible diagnoses, and taking steps in obtaining a definitive diagnosis, including possible referral to others. They must also have a clear understanding of the oral complications of surgical, medical, and radiologic treatment modalities and facilitate prevention and management of complications, best ensured by integrated comprehensive medical and dental oncology care teams.

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