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Failure to diagnose and delayed diagnosis of cancer

Medicolegal issues

Joel B. Epstein, DMD, MSD, FRCD(C); James J. Sciubba, DMD, PhD; Tammera E. Banasek, JD; Linda J. Hay, JD

Establishing a diagnosis requires that a series of events occurs in an appropriate sequence. This sequence is affected by the presence or absence of classic signs and symptoms, development of an index of suspicion for unexplained or unusual findings, appropriate and accurate diagnostic testing, and proper treatment and follow-up or referral. Each step is fraught with variability, requiring more than a simple analysis; failure to conduct a thorough analysis may lead to a misdiagnosis or delayed diagnosis. In oncology, such critical outcomes may result in the need for more aggressive treatment with increased morbidity, increased costs and an increased risk of dying of disease.

In patients with head and neck cancer (HNC) and oral squamous cell carcinoma (OSCC), delays in diagnosis of more than one month may contribute to an increased chance of diagnosis of later-stage

ABSTRACT

Background. Failure to diagnose and delayed diagnosis of cancer can have a significant effect on patients' morbidity and mortality. Oral health care professionals should be alert for oral premalignant and malignant disease and head and neck involvement by malignant disease. These issues have patient care and medicolegal implications.

Case Descriptions. To provide guidance to practitioners, the authors present a series of cases of oral and head and neck cancer that resulted in legal action. They chose the medicolegal cases to highlight dental professionals' potential legal liability and provide guidance in patient care.

Clinical Implications. Clinicians need to obtain complete comprehensive histories, perform thorough head and neck and oral examinations and appreciate the importance of being vigilant for abnormalities that may lead to early detection of potentially malignant disease.

Key Words. Oral cancer detection; oral cancer diagnosis; malpractice; risk management.

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Dr. Epstein is a professor, Department of Oral Medicine and Diagnostic Sciences, College of Dentistry, and Department of Otolaryngology and Head and Neck Surgery, College of Medicine and Cancer Center, University of Illinois at Chicago, 801 S. Paulina St., Room 556 (M/C 838), Chicago, Ill. 60612-7213, e-mail "jepstein@uic.edu". Address reprint requests to Dr. Epstein.

Dr. Sciubba is a retired professor, The Johns Hopkins School of Medicine, Baltimore, and is a consultant at The Milton J. Dance Head & Neck Cancer Center, Greater Baltimore Medical Center.

Ms. Banasek is an associate at Alholm, Monahan, Klauke, Hay and Oldenburg LLC, a law firm in Chicago. Ms. Hay is an owner of Alholm, Monahan, Klauke, Hay and Oldenburg LLC, a law firm in Chicago.

disease.¹ Furthermore, Fortin and colleagues² found that treatment delays of more than 40 days in early-stage HNC were associated with an increased risk of locoregional failure and an effect on survival. These authors recommended that patients with HNC should be treated in less than 30 days to achieve improved outcomes.² Results of a survey of North American radiation oncologists showed consensus that delays in initiating radiation therapy of approximately one month from referral were excessive and likely affected the outcomes.³ However, results from other studies did not demonstrate a statistically significant association between disease stage and delays in initiating treatment or the outcomes of therapy.^{4,5}

In a study conducted in the United Kingdom, Jones and colleagues⁶ reported a mean delay from general practitioners' referrals of patients with HNC to specialists of 5.1 weeks, a mean delay in performing magnetic resonance imaging of 5.6 weeks, and a mean time to treatment after referral of 10.3 weeks for radiation therapy and 5.2 weeks for surgery. These findings may not be typical in all countries or locations, but they point to the need to study ultimate outcomes in relation to diagnostic and treatment delays resulting from high demand, facility access challenges or policy constraints (such as insurance coverage restrictions). Nevertheless, the longest delay—4.9 months—from the onset of symptoms to seeking care or being referred for diagnosis appears to have been patient related.⁶

Researchers have recognized changes in the epidemiology of oropharyngeal cancer in people younger than 40 years who lack traditional tobacco or alcohol risk factors.⁷⁻⁹ In a study of 17 women younger than 40 years with OSCC of the anterior tongue, Vargas and colleagues⁷ found higher rates of recurrence and a shorter time to recurrence than they did in a comparable group of men and women older than 40 years. A review of the literature regarding lesions of the oral tongue showed higher rates of locoregional failure and mortality in patients younger than 40 years compared with those older than 40 years.⁸ However, mortality outcomes in the other two studies^{7,9} did not differ on the basis of age.

The 1998 National Health Interview Survey¹⁰ assessed the impact of cigarette smoking and alcohol consumption on receipt of periodic oral cancer examinations. The survey results revealed that tobacco use had no impact on the receipt of examinations, and alcohol use was associated

with a minimal impact on receipt of periodic oral cancer examinations.

Dentists may identify HNC at an earlier stage than do physicians. A survey of 51 new patients with OSCC showed that detection by dental care providers during a routine examination was associated with a less advanced stage of cancer at diagnosis.¹¹ In response to a survey question, 1,014 patients reported that 72.5 percent of dentists recognized early symptoms of HNC compared with 40.1 percent of physicians.¹² The responses to a mail survey of general medical and dental care providers showed that 58 percent of dentists routinely examined patients for signs of oral cancer, while physicians examined the mouth in response to patients' oral complaints.¹³ Only 15 percent of medical care providers reported feeling confident in their ability to detect oral premalignant or malignant lesions; this compares with 37 percent of dentists who reported feeling confident.¹³

Patton and colleagues¹⁴ conducted a survey of medical and dental care providers in North Carolina regarding the adequacy of training received in the detection of OSCC. Response rates ranged from 26 to 30 percent for medical care providers to 54 percent for dental care providers. Ninety-three percent of respondents stated that early detection improves five-year survival. More dental care providers (dentists, 99 percent; hygienists, 89 percent) than medical care providers (physicians and nurse practitioners, 78 percent) responded that they felt qualified to perform oral cancer examinations.¹⁴ Dental care providers felt adequately trained to conduct oral examinations, but they were less confident about conducting lymph node examinations than were medical care providers.

Most health care providers responded that training was adequate for oral cancer examinations (dentists, 89 percent; hygienists, 74 percent; physicians, 61 percent; nurse practitioners, 38 percent) and for lymph node examinations (dentists, 77 percent; hygienists, 64 percent; physicians, 98 percent; nurse practitioners, 97 percent). Seventy percent of dentists and

ABBREVIATION KEY. **CT:** Computed tomography. **HNC:** Head and neck cancer. **MRI:** Magnetic resonance imaging. **NPC:** Nasopharyngeal carcinoma. **OSCC:** Oral squamous cell carcinoma. **PET:** Positron emission tomography. **SCC:** Squamous cell carcinoma. **TMD:** Temporomandibular disorder. **TMJ:** Temporomandibular joint.

64 percent of hygienists felt inadequately trained in providing tobacco- and alcohol-use cessation services.

In a survey of general dentists, Horowitz and colleagues¹⁵ found that 81 percent of respondents stated that they performed oral cancer examinations in new patients older than 40 years. However, 86 percent of respondents stated that they did not conduct oral cancer examinations in edentulous patients.¹⁵ Only 26 percent of patients in Maryland reported having received an oral cancer examination in the previous year.¹⁶

A recent survey¹⁷ reported that 90 percent of general dental practitioners conduct examinations for cancer detection in new patients and more than one-half conduct examinations during annual visits. Two-thirds of dentists reported that they palpate cervical lymph nodes always or usually, but respondents performed intraoral palpation in less than one-third of patients. The authors found a relationship between the dentist's knowledge and time since graduation or participation in a continuing education course about cancer. Therefore, additional training is needed and should be tailored toward the professional groups involved in HNC and OSCC assessment.

We report a series of cases, accumulated from nationally derived practice settings, to identify the need for early and accurate diagnosis of head and neck malignancy and referral for treatment. We also present a summary of patient and medicolegal outcomes. We assembled these cases from the experience of two of us (J.B.E., J.J.S.) to emphasize the critical need for early recognition and diagnosis of malignant diseases involving the head and neck.

CASE REPORTS

Case 1. Epstein and Jones¹⁸ reported this case previously in a study of head and neck symptoms and findings in patients with nasopharyngeal carcinoma. An otolaryngologist referred a 23-year-old woman who did not use tobacco for evaluation of unilateral facial pain, limited jaw opening and jaw joint clicking; a tentative diagnosis of a temporomandibular disorder (TMD) had been made. The dentist identified left jaw joint clicking, limited jaw opening and masseter and pterygoid muscle tenderness, confirming the clinical diagnosis of TMD. The initial treatment for TMD was

not effective, and the clinician referred the patient back to the otolaryngologist. The otolaryngologist performed a second otolaryngologic examination and identified a nasopharyngeal lesion. Biopsy results confirmed that the lesion was a nasopharyngeal carcinoma (NPC) (later staged as a T4N3M0 lesion), which was treated with radiation therapy; however, the disease was not cured and the patient died. Legal action was initiated but was later dropped.

Case 2. A 15-year-old girl was referred by her orthodontist to an oral and maxillofacial surgeon for extraction of an impacted maxillary right third molar after completion of orthodontic treatment of four years' duration. At a postsurgical visit, the surgeon noted a mass in the posterior aspect of the hard palate and performed a biopsy.¹⁹ A histopathologic examination revealed a low-grade mucoepidermoid carcinoma of a minor palatal salivary gland (staged as T1N0M0, stage I disease). An otolaryngologist performed a partial maxillectomy, and the final diagnosis was T2N0M0 intermediate-grade mucoepidermoid carcinoma with a positive surgical margin noted.

The patient received radiation therapy (tumoricidal dose of 6,600 centigrays). A review of pretreatment orthodontic study models revealed a palatal mass. In addition, pretreatment radiographs revealed superior displacement of the developing ipsilateral maxillary third molar not seen on the opposite side of the mouth. Both the study models and the radiographic findings provided evidence of the lesion's presence at the initiation of orthodontic therapy, some four years before diagnosis and treatment. The claim of failure to diagnose was settled by the orthodontist's insurance carrier.¹⁹

Case 3. A 50-year-old woman with a history of tobacco and alcohol abuse visited her physician because of a recurring ulceration on the tongue. The physician identified the lesion on initial examination, but on follow-up within the month no longer detected the lesion. The patient later visited her physician for other reasons, and he did not observe the presence of an oral lesion. During two subsequent visits to her dentist, the patient underwent extractions in the left mandible, and the dentist did not identify any mucosal lesions. Nine months after the physician made the initial diagnosis of an ulceration, he identified a lesion

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and referred the patient to an oral and maxillofacial surgeon for a biopsy, the results of which confirmed a diagnosis of squamous cell carcinoma (SCC) (stage T1N0M0).

The patient refused surgery and received radiation therapy to a total dose of 7,000 cGy, with concurrent cisplatin chemotherapy as a radiation sensitizer. Although she responded initially, her physician identified a recurrence six months after completion of radiation therapy and chemotherapy. The physician recommended salvage surgery, but the patient refused. She was treated with palliative home care and hospice care for two years after receiving the diagnosis and died of the disease. Legal action based on an alleged delayed diagnosis was settled before the case reached trial.

Case 4. A 58-year-old man visited an oral and maxillofacial surgeon because of a white area on his tongue that the patient had identified one year earlier. He described it as recurrent but not chronic or progressive. The patient reported a 30-year history of smoking one-half pack per day (a 15-pack-year history) but had stopped smoking one year earlier. He reported consuming one alcoholic drink per day. The patient reported that the white lesion had recurred and, on examination, the surgeon observed an ulceration (< 1 centimeter) on the lateral aspect of the tongue, with no lymph node enlargement. The oral and maxillofacial surgeon performed an excisional biopsy. The specimen was submitted for histopathological review but it was not received at the laboratory; thus, the surgeon did not obtain a histologic confirmation.

The surgeon conducted clinical follow-up examinations and did not observe any recurrence at six months. However, nine months after the biopsy, the surgeon noted an enlarged ipsilateral jugulodigastric lymph node that had increased rapidly in size after being identified two months earlier. Computed tomography (CT) revealed that the lymph node was 3.0 × 2.5 cm; subsequent positron emission tomographic CT studies did not reveal other findings.

The results of a fine-needle aspiration biopsy were suspicious for SCC, and an otolaryngologist-head and neck surgeon conducted staging endoscopy. The surgeon did not observe a primary lesion, and the tongue was free of disease, with staging as TXN2M0. During subsequent surgery, the surgeon did not see a primary lesion and excised the fixed lymph node (measuring 4.0 × 3.5 cm) in the jugulodigastric region. The results

of multiple blind biopsies of the tonsils, base of the tongue, nasopharynx and pyriform sinus were negative. The patient received postoperative radiation therapy (total dose, 6,500 cGy). However, four months after completion of radiation therapy, the patient's physician identified multiple metastases to bone and lung, and the patient died four months later. The tongue lesion had not recurred, and no other primary cancer had been identified. A wrongful death lawsuit was settled before the case reached trial.

Case 5. A 68-year-old edentulous man was referred by his physician to one of us (J.B.E.) for diagnosis of a mass that had been present for more than one year in the mucosa of the left maxillary residual ridge. The patient had seen a denturist seven times in the previous year for denture adjustment because of pressure and discomfort in the region. (**Editor's note:** According to American Dental Association policy, a denturist is educationally unqualified to practice dentistry in any form on the public.) When his physician identified the mass, the patient was referred for tissue diagnosis. The exophytic firm lesion with surface ulceration measured 3 × 1 cm; the denture had been relieved extensively to allow the prosthesis to be placed over the lesion.

Radiographs revealed bone destruction extending to the maxillary sinus floor. Biopsy results confirmed a diagnosis of SCC, which was staged as T4N0M0. The patient underwent a partial maxillectomy and received postsurgical radiation therapy; in addition, a maxillofacial prosthodontist placed an obturator. The claims of delayed diagnosis or failure to diagnose and failure to refer were settled by the denturist's insurance carrier.

Case 6. A 50-year-old man visited his general dentist and a periodontist at alternating three-month appointments for routine oral hygiene care. The patient did not smoke or drink alcohol. The periodontist noted a white lesion measuring 9 × 3 millimeters on the lateral side of the tongue near a recently placed implant and crown. The clinician made adjustments to the crown.

Six months later, an area of the patient's tongue became sore and remained sore for the next 10 months. The dentist made further adjustments to the crown. Sixteen months after the leukoplakia was first observed, the lesion had progressed to a 12- × 12-mm ulceration on the anterolateral tongue. Biopsy results revealed SCC, which was staged as T2N1M0. Resection and two courses of irradiation were unsuccessful

in curing the disease. The patient died one year after receiving the diagnosis. A claim by the patient's surviving children was settled before litigation.

DISCUSSION

The medicolegal implications of a delayed or missed diagnosis of oral malignant disease can be severe. Cases alleging failure to diagnose cancer and failure to refer patients for an additional opinion and treatment are likely to be cases with large damage claims owing to the cost of the medical care, pain and suffering, potential permanent disfigurement, lost wages or income claims and loss of spousal companionship, which all are attributed to the injury. Legal concerns also are affected by the quality and completeness of a patient's dental and medical records, which often compound legal liability issues when the records are inadequate or incomplete.

Signs and symptoms must be sufficient to lead a patient to seek professional care, and they must be sufficient for the health care provider to recognize an abnormality and establish a diagnosis. Dental and medical care providers need increased formal training to improve the detection and recognition of oral abnormalities, as well as to lead to appropriate steps to achieve an accurate diagnosis. In cases of uncommon and unusual diseases, clinicians should consult health care providers who have additional training and experience.

Symptoms. Variations of normal and fluctuating symptoms (such as mild sensitivity or discomfort) may reduce the probability of diagnosing cancer. Oral premalignant lesions and early-stage cancers typically are asymptomatic or involve few symptoms, but they advance over time and may lead to symptoms that may include discomfort, pain, limited movement of the involved structure (for example, tongue or soft palate), an ulcerated mass and/or bleeding from the involved site. In cases of advanced disease, symptoms may include a mass at the primary site, with lymph node involvement, limited function (tongue movement, dysphagia), weight loss, bleeding and/or neurologic symptoms.

A malignant disease likely is the most significant condition a dental care provider may diagnose. However, evidence shows that primary

dental care providers either do not perform such oral examinations routinely or perform limited or inadequate examinations,^{10,17} which may result in litigation claims for failure to diagnose oral cancer.²⁰

The cases presented in this report involved allegations of delayed or incorrect diagnoses leading to significant morbidity and mortality. The reasons for this suboptimal performance are multifactorial and may include a lack of training, lack of or inadequate remuneration, early signs that may be minimal or subtle and/or the low perceived prevalence of this disease, resulting in a low index of suspicion.^{13,14} The separation of medicine and dentistry, the nature of dental practice and the prevalence rate of HNC can make diagnosis challenging; however, considerable medicolegal implications exist.

Diagnostic studies. To make an accurate diagnosis, clinicians must select the most appropriate diagnostic tests and ensure that the tests are conducted appropriately and the results are interpreted appropriately. In cases in which a tissue biopsy is necessary, biopsy site selection, technique and quality of the tissue specimen affect the pathologist's ability to reach an accurate diagnosis. Investigators have shown significant variability in pathological diagnoses, with inter-rater and intrarater diagnostic varia-

tion²¹; therefore, the pathologist's experience is as important as the experience of the clinician who obtained the tissue. In a study of patients with oral premalignant lesions, Fischer and colleagues^{21,22} found that use of the punch biopsy instrument resulted in reduced variability and more consistent outcomes. Tissue evaluation may require use of special stains and techniques (such as flow cytometry and immunohistochemistry) after the pathologist has conducted a preliminary review. These findings reinforce the need to establish a clinical differential diagnosis or impression before submitting the tissue for evaluation.

Some studies, such as direct immunofluorescence, require specific tissue transport media and planning at the time of the biopsy. If the histopathologic diagnosis is not consistent with the clinical appearance or behavior of the lesion, further investigation is required to achieve a definitive diagnosis; this may include repeating the initial studies, performing additional testing

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or referring the patient to a more experienced health care provider. In addition, there are conditions such as proliferative verrucous leukoplakia for which a clinical diagnosis is supported by histologic findings but is not based on histopathologic findings alone.^{23,24} In these cases, experienced dental care providers working in concert with pathologists and other health care providers can facilitate the diagnosis.

Moreover, incisional biopsy and other tissue techniques including exfoliative cytology, brush cytology and fine-needle aspiration, which involve cell collection and interpretation on a tissue smear, are subject to variability in interpretation by pathologists. Molecular techniques may add information to that obtained in tissue evaluation and increase the accuracy of the tissue diagnosis. Additional diagnostic testing may include imaging (for example, dental radiographs, CT), the results of which require interpretation by radiologists and other health care providers; such testing is subject to the limitations of the imaging modality chosen and the variability in training and experience of the radiologists.

Case 1. The patient with NPC exhibited symptoms that overlap those of TMD. Patients with advanced NPC may have lymphadenopathy and skull-base involvement that may produce multiple cranial neuropathies, further complicating the presentation profile. Reiter and colleagues²⁵ reviewed nine cases of NPC that originally were diagnosed as TMD; they noted overlapping symptoms, including earache or other otologic, nasal or paranasal symptoms; facial pain; and trismus, as reported in a review of patients admitted for treatment of NPC.¹⁸

In a case series of 52 consecutive patients with NPC, Epstein and Jones¹⁸ reported that the diagnosis was incorrect in 19 percent of cases, with the majority of patients thought to have an ear, nose or throat infection and 2 percent TMD. The mean delay from manifestation of initial signs and symptoms to diagnosis was 8.3 months (range, one to 36 months). Pain was the most common complaint, described as a headache or an earache and jaw pain in 12.5 percent of patients; 13.5 percent of patients had other symptoms commonly associated with TMD, with key differentiating symptoms including nosebleed, nasal symptoms, reduced hearing and/or a neck mass.¹⁸ The delayed diagnosis in case 1 was unrelated to the patient's dental care, owing to the negative findings of the nasopharyngeal endoscopic exami-

nation conducted before she was referred for management of orofacial pain. However, on reexamination of the nasopharynx, the clinician diagnosed previously undetected occult NPC.

Case 2. In the case of the patient with mucoepidermoid carcinoma of the palate, the diagnosis was delayed for years, which likely permitted the disease to progress to a more advanced stage, requiring more aggressive treatment and resulting in increased morbidity. Experts in the case and defense counsel did not believe that the lack of a relationship between the orthodontic treatment and the carcinoma would be a successful defense, and the defendant's insurance carrier settled the case before trial. All health care professionals, regardless of their specialization, should be trained to recognize pathology in the head and neck and be on the lookout for it.

Cases 3 and 4. The case of recurrent ulceration and poor response to therapy (case 3) represents a failure to diagnose and a delayed diagnosis. In case 4, the pathology laboratory did not receive the initial biopsy specimen, making diagnosis impossible and resulting in advanced disease. This case demonstrates the need to record details of the biopsy procedure and specimen submission, as well as to follow up with both the patient and the laboratory if the clinician does not receive laboratory test results within a reasonable time frame.

Cases 5 and 6. Case 5 represents a delayed diagnosis with a poor outcome. Case 6 represents the need for a thorough examination, consistent record keeping and effective communication between referring health care providers (in this case, a general dentist and periodontist). One clinician noted the presence of a lesion, while the other did not, which likely led to a delay in biopsy and diagnosis.

Oral manifestations of disease. Patients with advanced HNC may seek care because of symptoms, which increases the likelihood of recognition, leading to a correct diagnosis (Table). Oral manifestations of disease that is not SCC also may occur. Dental care providers must maintain an index of suspicion to recognize abnormalities that may reflect hematologic malignancy such as pallor, fatigue, petechiae, hematoma, gingival and lesion bleeding, and limited inflammatory response to infection or trauma. In addition, metastatic disease from distant primary cancers may manifest in the head and neck with pain, numbness, tooth mobility, a mass or radiographic changes. In the

TABLE

Possible symptoms and signs of oral involvement by malignant disease.*

DISEASE AND STAGE	SYMPTOMS	SIGNS	IMAGING AND TESTING†
Squamous Cell Carcinoma			
Early stage	None, discomfort	Irregular white and/or red lesion, ulceration, oral mass, friable tissue	None
Advanced stage	Limited function, numbness, pain, bleeding, dysphagia, dysarthria, weight loss, oral or neck mass	Mass, necrosis, bone invasion, lymph node involvement	Dental radiographs: occasional bone involvement, regional lymph node involvement; MRI‡/CT§: bone and/or soft-tissue involvement, including regional lymph nodes; PET¶-CT; bone scan
Salivary Gland Cancer			
Major salivary gland			
Early stage	None, mass, gland swelling	None, mass, swelling, secondary bacterial sialadenitis	MRI, CT
Advanced stage	Mass, regional lymph node involvement, numbness, discomfort, paresis/paralysis	Mass, regional lymph node involvement, numbness, paresis/paralysis	MRI, CT
Minor salivary gland			
Early stage	None, mass, gland swelling, discomfort	Mass, mucosal ulceration	None
Advanced stage	Neck mass, numbness, sinus symptoms (antral involvement)	Sinus complaints, dysfunction, dysarthria, dysphagia	CT findings positive: palatal bone invasion, sinus involvement
Lymphoma			
Early stage	None, fatigue, malaise, fever (B symptoms#), mass	Rubbery mass (intraoral and cervical lymph nodes)	Biopsy, dental radiographs, cone beam imaging, CT: bone involvement, soft-tissue involvement
Advanced stage	Pallor, petechiae (indicative of marrow involvement)	Necrosis, ulceration, secondary infection	Biopsy, dental radiographs, cone beam imaging, CT: changes in complete blood cell count, bone involvement, soft-tissue involvement
Leukemia			
Early stage	Fatigue, malaise, easy bruising, bleeding and/or enlarged gingiva, pallor, viral reactivation and/or secondary or recurrent infections	Gingival enlargement with or without erythema, soft-tissue necrosis with limited inflammation, progressive and/or necrotizing infection, bad breath and/or bad taste, tissue pallor, petechiae/ecchymoses/hematoma, poor healing with tissue manipulation	Imaging: alveolar bone change; complete blood cell count
Advanced stage	Limited inflammatory response, infection with limited symptoms	Same as above	Imaging: alveolar bone change; complete blood cell count
Metastatic Disease	Numbness, pain, tooth mobility, history of malignancy	Tooth mobility, unilateral anesthesia, gingival or soft-tissue mass rare	Imaging: radiolucent and/or mixed radiolucent-radiopaque lesion of the posterior mandible
Nasopharyngeal Carcinoma			
Early stage	None	Neck node, stuffy nose, nosebleed (signs less likely at this stage)	Nasopharyngoscopy, CT, MRI
Advanced stage	Facial, ear and/or TMJ** pain, headache, numbness, cervical lymph node enlargement, plugged ear, stuffy nose, nosebleed, nasal-sounding speech	Neck node, stuffy nose, nosebleed	Nasopharyngoscopy, CT, MRI
Sarcoma	Discomfort and/or pain, numbness, mass, limited function	Soft-tissue mass with or without ulceration, bony mass	Dental radiographs, cone beam imaging, CT, MRI
Melanoma	None, discomfort and/or pain, numbness, bleeding	Pigmented (rarely nonpigmented) lesion: flat or elevated, with or without ulcer	Imaging

* This is a brief summary of symptoms and signs and is intended only as a guide. General and more common symptoms and signs are presented; this is not an exhaustive list. Symptoms and signs vary, depending on location and stage of disease; typically, there are few symptoms at onset. However, they often advance and increase with disease progression. Determination of disease cannot be made on the basis of a single finding or a combination of findings, but requires a general understanding of the specific condition and location of the tumor, diagnostic testing and/or referral.

† Biopsy may be indicated for oral lesions/bone changes in all conditions.

‡ MRI: Magnetic resonance imaging.

§ CT: Computed tomography.

¶ PET: Positron emission tomography.

B symptoms: General symptoms that may be present in people with lymphoma, including lymph node enlargement, weight loss and night sweats.

** TMJ: Temporomandibular joint.

case of suspected inflammatory or traumatic lesions, removal of the potential cause and confirmation of resolution commonly are recommended at a two-week follow-up visit; however, clinicians should consider this approach only for patients who can be expected to comply with follow-up. If the clinician identifies highly suspicious lesions, tissue diagnosis should not be delayed.

Delays in diagnosis are common allegations in legal actions involving patients with HNC.²⁶ In 2001, the average cost of defending medical malpractice claims in the United States was \$28,801 per case, and the median damages award in medical malpractice cases was \$1 million in 2001.²⁷ In 49 percent of cases of HNC, biopsies allegedly were indicated but not performed.²⁶ In these cases, the allegations included delays in diagnosis in the face of signs and symptoms consistent with or suggestive of cancer.

Jury verdict reviews. Lydiatt²⁰ obtained jury verdict reviews for 50 cases of HNC from a legal database (Westlaw, West Publishing, St. Paul, Minn.) of all state and federal cases from 1984 to 2000. The outcomes of these cases from 21 states were as follows: defendants won (42 percent), plaintiffs won (32 percent) and the parties reached a settlement (26 percent).²⁰ The most common allegations were failure to diagnose, failure to perform a biopsy, failure to refer and surgical complications.

The cases identified by Lydiatt²⁰ were associated with young patients (mean age, 45 years); in 47 percent of these cases, the patients died. In patients younger than 47 years, misdiagnosis was alleged in 19 percent of cases, with awards (60 percent of cases) averaging \$755,824.²⁰ Patients older than 47 years received awards averaging \$495,417.

Plaintiffs alleged a failure to diagnose in 86 percent of cases, which involved general medical care providers (100 percent), otolaryngologists (89 percent) and dentists (85 percent), the majority of whom were general practitioners.²⁰ If the delay in diagnosis was three months or less, a verdict in favor of the defendant was found in 86 percent of cases; if the delay was more than three months, a verdict in favor of the defendant was found in only 40 percent of cases.²⁰ Plaintiffs also com-

BOX**Detailed patient records pertaining to oral lesions.*****EXAMINATION FINDINGS**

- Head and neck abnormalities (for example, asymmetry, masses, cranial nerve abnormalities)
- Lymph node assessment: location, size (millimeters), texture (soft, firm, hard), tender or nontender, mobile or fixed
- Lesion: location, size (length × width), color (red, white, mixed), surface (ulcerated, smooth, verrucous, fissured), elevation (none or thickness in millimeters), photographic documentation, adjunctive test results
- Radiographic alterations: site, quality, size
- Other findings

**CLINICAL IMPRESSIONS/DIFFERENTIAL DIAGNOSIS
TREATMENT PLAN/PROCEDURES**

- Diagnostic test request or referral, decide to perform biopsy (site selection, technique, quality of specimen), histopathologic examination findings (special stains and/or tests), interpretation by pathologist
- Review test results with clinical findings; if nondiagnostic or conflicting, repeat test or order different test, refer patient, document findings
- Referral: record patient's name, date of appointment
- Follow-up plan: repeat examination and record findings, record test results or referral reports

* Maintaining detailed records allows the clinician to assess a lesion's progress and the nature of changes. Treatment plan records document variability of each step owing to patient and clinician variables (for example, experienced clinician and pathologist, consultations with other health care providers, oncology centers/teams).

monly alleged failure to perform a biopsy and failure to refer.²⁰ Judgments in 45 percent of the 50 lawsuits were against dental care providers, with 60 percent of these cases alleging that the dentist did not perform a biopsy.²⁰

Risk management. Therefore, to reasonably manage risk, health care providers must endeavor to recognize abnormalities, conduct diagnostic procedures without delay (for example, a biopsy) and reach a definitive diagnosis (after obtaining informed consent) or refer the patient to a more experienced dental or medical care provider who can make the diagnosis relative to the initial signs and symptoms. The length of delay that is harmful is unknown, as the impact of a delay on patient outcomes is not well documented. However, from a legal perspective, particularly in cases of inadequate documentation, a delay in diagnosing or referring a patient could be costly.

Malpractice claims. Although the requirements may vary from state to state, in a claim filed for professional malpractice, the plaintiff or the representative of the patient generally must prove certain elements before he or she can recover a judgment. Those elements typically include a duty owed by the professional to that patient (in other words, there was some type of dentist-patient relationship), there was a breach

of that duty (commonly known as a breach of the standard of care) and the injury was proximately caused by the deviation from the standard of care.^{28,29}

Expert testimony. A deviation from the standard of care almost always must be established through expert testimony, meaning that a professional with expertise in the area of care will state openly under oath that the defendant dentist breached the standard of care. The requirements and qualifications of the expert will vary, but generally he or she must have a license the same as or similar to that of the defendant and have experience in or otherwise be qualified to render opinions in the area of practice that is at issue.²⁸ From a practical perspective, that typically requires liability experts in cases involving dental care providers to have had dental training, experience and licensure similar to those of the defendant dentist, as well as some expertise in the area at issue.

Regarding the issue of proximate cause and injury, which often is a key defense in a case involving failure to diagnose cancer, the range of experts available to both plaintiffs and defendants is far greater than it is for other illnesses because causation and damages experts are not limited to those with dental expertise and licensure, but rather include many types of medical care providers with expertise in a variety of specialties, including otolaryngologists—head and neck surgeons, oncologists, pathologists and other physicians. Regarding the specific issue of damages, even more experts are available to develop treatment plans for the injured party and to determine future costs of care and the time value of a lost opportunity to earn money.

Lawsuits in dental and medical malpractice cases are decided on the basis of facts and applicable law.²⁹ If a judgment is entered in favor of a plaintiff, the result is calculated in a dollar value. In cases involving serious injuries, the potential award for disability and disfigurement can carry a high value, as can the potential value for past and future medical care expenses, loss of income, and pain and suffering. In a potential defense, the judge may give consideration to a patient's lack of cooperation with the health care provider.

Although the facts and law determine the outcome, intangible factors in a case involving allegations of a failure to diagnose cancer can drive the dollar value higher, including issues such as sympathy generated by the plaintiff or the plain-

tiff's family and/or animosity toward the defendant. These factors combined make a case involving a claim of failure to diagnose cancer a serious risk for the health care provider.

It is not surprising that a poor patient outcome appears to be related to a judgment against the health care provider.²⁶ However, a poor outcome is not evidence of malpractice or negligence, but it absolutely will increase the odds that an injured party will pursue a lawsuit. The amount of an award or settlement appears to be related to mortality or extent of the morbidity or disability,²⁶ and it is this potential that will drive the lawsuit.

Need for documentation. The most common allegation in malpractice cases involving HNC is a delay in diagnosis. Frequently, plaintiffs are younger than expected, and delays in diagnosis and treatment are associated with increased morbidity and possibly poorer outcomes.^{20,26} Poor outcomes might be associated with a delay in diagnosis, stage of the disease or biological activity of the disease. An adequate defense in oral cancer cases requires clear and consistent documentation of clinical information. Many cases can be defended on the basis of the aggressiveness of the cancer but only with adequate documentation of clinical findings, clinical impressions and outcomes of tests and biopsies (Box). Because patients' refusal to undergo recommended procedures can independently form the basis of a defense,²⁶ practitioners also must document these actions.

CONCLUSION

The purpose of this article is to emphasize the need for dental professionals to obtain comprehensive histories, be vigilant, perform thorough head and neck and oral examinations, and appreciate that all providers should be alert for abnormalities that may represent potentially malignant disease. We chose these medicolegal cases to highlight the importance of dental professionals' examining patients for oral premalignant and malignant disease and head and neck involvement by malignant disease, to provide guidance in patient care and to review the possible impact of health care providers' potential legal liability. ■

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Nothing in this article is intended nor should it be construed to create or provide any legal standard of appropriate care or practice or to provide legal advice. Rather, every factual scenario must be evaluated on its own merits as to any proper standard of care and with regard to any potential specific causal link to injury.

1. Allison P, Locker D, Feine JS. The role of diagnostic delays in the prognosis of oral cancer: a review of the literature. *Oral Oncol* 1998;34(3):161-170.
2. Fortin A, Bairati I, Albert M, Moore L, Allard J, Couture C. Effect of treatment delay on outcome of patients with early-stage head-and-neck carcinoma receiving radical radiotherapy. *Int J Radiat Oncol Biol Phys* 2002;52(4):929-936.
3. Mackillop WJ, Zhou Y, Quirt CF. A comparison of delays in the treatment of cancer with radiation in Canada and the United States. *Int J Radiat Oncol Biol Phys* 1995;32(2):531-539.
4. Barton MB, Morgan G, Smee R, Tiver KW, Hamilton C, Gebiski V. Does waiting time affect the outcome of larynx cancer treated by radiotherapy? *Radiother Oncol* 1997;44(2):137-141.
5. Trotti A, Klotch D, Endicott J, Ridley M, Cantor A. Postoperative accelerated radiotherapy in high-risk squamous cell carcinoma of the head and neck: long-term results of a prospective trial. *Head Neck* 1998;20(2):119-123.
6. Jones TM, Hargrove O, Lancaster J, Fenton J, Shenoy A, Roland NJ. Waiting times during the management of head and neck tumours. *J Laryngol Otol* 2002;116(4):275-279.
7. Vargas H, Pitman KT, Johnson JT, Galati LT. More aggressive behavior of squamous cell carcinoma of the anterior tongue in young women. *Laryngoscope* 2000;110(10 part 1):1623-1626.
8. Sarkaria JN, Harari PM. Oral tongue cancer in young adults less than 40 years of age: rationale for aggressive therapy. *Head Neck* 1994;16(2):107-111.
9. Friedlander PL, Schantz SP, Shaha AR, Yu G, Shah JP. Squamous cell carcinoma of the tongue in young patients: a matched-pair analysis. *Head Neck* 1998;20(5):363-368.
10. Macek MD, Reid BC, Yellowitz JA. Oral cancer examinations among adults at high risk: findings from the 1998 National Health Interview Survey. *J Public Health Dent* 2003;63(2):119-125.
11. Holmes JD, Dierks EJ, Homer LD, Potter BE. Is detection of oral and oropharyngeal squamous cancer by a dental health care provider associated with a lower stage at diagnosis? *J Oral Maxillofac Surg* 2003;61(3):285-291.
12. Gellrich NC, Suarez-Cunquero MM, Bremerich A, Schramm A. Characteristics of oral cancer in a central European population: defining the dentist's role. *JADA* 2003;134(3):307-314.
13. Macpherson LM, McCann MF, Gibson J, Binnie VI, Stephen KW. The role of primary healthcare professionals in oral cancer prevention and detection. *Br Dent J* 2003;195(5):277-281; discussion 263.
14. Patton LL, Ashe TE, Elter JR, Southerland JH, Strauss RP. Adequacy of training in oral cancer prevention and screening as self-assessed by physicians, nurse practitioners, and dental health professionals. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2006;102(6):758-764.
15. Horowitz AM, Drury TF, Goodman HS, Yellowitz JA. Oral pharyngeal cancer prevention and early detection: dentists' opinions and practices. *JADA* 2000;131(4):453-462.
16. Horowitz AM, Canto MT, Child WL. Maryland adults' perspectives on oral cancer prevention and early detection. *JADA* 2002;133(8):1058-1063.
17. Lehew CW, Epstein JB, Kaste LM, Choi YK. Assessing oral cancer early detection: clarifying dentists' practices [published online ahead of print Sept. 17, 2009]. *J Public Health Dent*.
18. Epstein JB, Jones CK. Presenting signs and symptoms of nasopharyngeal carcinoma. *Oral Surg Oral Med Oral Pathol* 1993;75(1):32-36.
19. Epstein JB, Hollender L, Pruzan SR. Mucoepidermoid carcinoma in a young adult: recognition, diagnosis, and treatment and responsibility. *Gen Dent* 2004;52(5):434-439.
20. Lydiatt DD. Cancer of the oral cavity and medical malpractice. *Laryngoscope* 2002;112(5):816-819.
21. Fischer DJ, Epstein JB, Morton TH Jr, Schwartz SM. Reliability of histologic diagnosis of clinically normal intraoral tissue adjacent to clinically suspicious lesions in former upper aerodigestive tract cancer patients. *Oral Oncol* 2005;41(5):489-496.
22. Fischer DJ, Epstein JB, Morton TH, Schwartz SM. Interobserver reliability in the histopathologic diagnosis of oral pre-malignant and malignant lesions. *J Oral Pathol Med* 2004;33(2):65-70.
23. Morton TH, Cabay RJ, Epstein JB. Proliferative verrucous leukoplakia and its progression to oral carcinoma: report of three cases. *J Oral Pathol Med* 2007;36(5):315-318.
24. Cabay RJ, Morton TH Jr, Epstein JB. Proliferative verrucous leukoplakia and its progression to oral carcinoma: a review of the literature. *J Oral Pathol Med* 2007;36(5):255-261.
25. Reiter S, Gavish A, Winocur E, Emodi-Perlman A, Eli I. Nasopharyngeal carcinoma mimicking a temporomandibular disorder: a case report (published correction appears in *J Orofac Pain* 2006;20[2]:106. Winocur, Ephraim added). *J Orofac Pain* 2006;20(1):74-81.
26. Lydiatt DD. Medical malpractice and head and neck cancer. *Curr Opin Otolaryngol Head Neck Surg* 2004;12(2):71-75.
27. Employment Policy Foundation. Medical malpractice litigation raises health care cost, reduces access and lowers quality of care. June 19, 2003. "web.archive.org/web/20041030013924/www.epf.org/pubs/newsletters/2003/ib20030619.pdf". Accessed Sept. 24, 2009.
28. Sullivan v. Edward Hospital, 209 Ill.2d 100, 806 N.E. 2d 645, 282 Ill. Dec. 348, 2004 Ill. Lexis 352 (2004).
29. Bowman v. University of Chicago Hospitals, et al, 366 Ill. App. 3d577, 852 N.E. 2d 383, 2006 Ill. App. Lexis 540, 304 Ill. Dec. 133 (2006).