

Evaluating, documenting and following up oral pathological conditions

A suggested protocol

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In the course of providing comprehensive dental treatment, practitioners may encounter suspicious radiographic or mucosal changes that are variations from what is considered normal, but lack the typical features of malignancy, and may require observation over time. Alternatively, dentists might perform a biopsy of a clinically suspicious lesion, which results in a pathological diagnosis other than frank malignancy or premalignancy.

There is little guidance in the literature on when and how to follow up lesions that have a low index of clinical suspicion.

Numerous protocols have been published for postsurgical follow-up of patients who have had malignancies removed, but little guidance is provided in the literature for monitoring an area of suspicious clinical appearance or one that yields an equivocal pathological diagnosis on biopsy or repeated biopsy. This can create a dilemma for a dentist deciding how to proceed with such patients. Guidelines or recommendations for following up and documenting a suspicious area over an extended

period are not readily available.

During the past 20 years, few dental textbooks or articles that address the topic of biopsy have provided any discussion on the nuances of clinically following up suspicious lesions that have the potential to result in adverse effects on the health of the patient. They do not discuss how frequently patients should undergo examinations, what information to include in patient records or when to make the decision to consult with a second health professional or to perform a second biopsy of the tissues. Anecdotally, graduates of various dental schools

Background. Many textbooks and articles are available to assist dentists in examining patients, establishing diagnoses for oral lesions and understanding the techniques of biopsy. There is little guidance in the literature, however, on when and how to follow up lesions that have a low index of clinical suspicion, or for which the pathological diagnosis does not demonstrate any overt signs of malignancy or premalignancy.

Types of Studies Reviewed. The authors reviewed the literature, talked to numerous clinicians and sought legal opinions regarding how a reasonable and prudent dentist should manage patients with clinically evident oral lesions that do not suggest any adverse long-term effects on the health and safety of the patient.

Results. The few guidelines available in the literature, coupled with the observations of the authors and others, allow logical and reasonable interim recommendations to be proposed regarding the frequency of examinations, the timing of invasive procedures and medicolegally prudent documentation guidelines. Future studies are needed to refine these recommendations.

Clinical Implications. Some dentists have been sued for alleged failure to monitor patients, document cases or refer patients with oral lesions. The recommendations provided here can help dentists manage these patients, but they should not be construed as being rigid guidelines or legal standards that apply to all clinical situations. In some cases, the judgment and experience of clinicians may indicate the need to deviate from these recommendations. Refinements of these guidelines may emerge on the basis of future studies.



have remarked that little guidance was provided in their dental training in regard to developing a structured plan for monitoring suspicious lesions in patients, which would yield a favorable outcome for the patient while providing reasonable medicolegal protection for the practitioner. The amount of litigation that is occurring for alleged failure to adequately follow up with or refer such patients suggests that this may be an area of confusion for clinicians and attorneys alike. We will examine various facets of this clinical problem and offer some generalized recommendations for dental practitioners to consider.

REVIEW OF THE LITERATURE

The focus of most oral surgery and pathology textbooks typically has been on examination of patients, classification and differential diagnosis of lesions, biopsy procedures and protocols for submission of specimens.¹⁻¹² The existing texts present no in-depth discussions of protocols for following up suspicious lesions (that is, departures from what we know as normal) over time, but rather provide vague recommendations, such as diagnostic observation for 10 to 14 days if there is not a high degree of suspicion of malignancy.

Golden and Hooley⁴ endorsed a 10- to 14-day initial observation period, but this recommendation appears to have been influenced by Peterson and associates.³ King and McGuff¹² offered general prebiopsy guidance (that is, wait a week or 10 days unless the characteristics suggest a cancerous lesion), but the authors do not address the issue of follow-up for a lesion that continues to have a non-threatening appearance or for which the histopathologic findings show no malignant changes.

WHO SHOULD EVALUATE?

In many practices, it is not uncommon for dentists to unofficially delegate responsibility for soft-tissue lesion screenings to the practice's dental hygienist. Although we find that dental hygienists generally are well-trained to perform cancer screening examinations and most feel comfortable in this role, this places a great deal of responsibility on both the dentist and hygienist. Many dental hygienists have told us that their greatest concerns arise when the dentists they work for fail to heed their findings of positive results and do not perform a thorough confirmatory examination. In our opinion, the ultimate responsibility for diagnosis and follow-up rests with the dentist, and delegation does not relieve

him or her of this responsibility. Other authors have expressed this opinion.¹³ In most, if not all, states, delegation of this responsibility is not permitted by law.

If the general dentist decides to refer the patient for a biopsy or other diagnostic testing, we recommend that the appointment be arranged, if possible, at the time the decision is made to refer (that is, while the patient is still in the office). A confirmation letter, fax or e-mail subsequently should be sent to the specialist, outlining the dentist's concerns and requesting a written report of the results of the specialist's evaluation of the patient. We recommend that copies of all correspondence and biopsy reports be retained in patients' records.

Referring general dentists should have confidence in the specialists with whom they work. This has become a problem for some providers in this era of managed health care. Some medical and dental health care organizations reportedly refuse to authorize use of recognized dental specialists, such as oral and maxillofacial surgeons and pathologists. In our opinion, biopsy specimens should be submitted to oral and maxillofacial pathologists for evaluation whenever possible, because they have enhanced skills in diagnosing changes in the tissues indigenous to the oral cavity and contiguous structures. Although competent in general pathological principles, some general medical pathologists are unfamiliar with the histopathologic subtleties of odontogenic and oral tissues, which can lead to misdiagnoses. Likewise, oral and maxillofacial surgeons generally are more familiar with the subtleties of the tissues of the oral cavity and its contiguous structures than are most physicians.

Dentists also should make sure that all inter-office communications receive timely attention. We are aware of at least one case that went into litigation because the biopsy report of a malignant lesion wound up at the bottom of a pile of routine mail and paperwork on a doctor's desk, where it lay undiscovered for many days. All offices performing biopsies should have reasonable policies and procedures in place to ensure timely review, documentation and follow-up actions for returned biopsy reports.

WHEN TO PERFORM A BIOPSY

Unfortunately, the public generally perceives the term "biopsy" in a negative manner, believing its purpose is to verify a diagnosis of cancer. This is

dilemmas.¹⁴ In actuality, verifying malignancy is

need to be counseled that the primary purpose of a biopsy is to arrive at a precise diagnosis that will lead to proper management, since many lesions have similar clinical appearances. A biopsy is more likely to rule out a diagnosis of cancer or lead to an alternate diagnosis.

The indications for biopsy rarely are defined completely in the literature. We believe that the list shown in the box ("Indications for Biopsy"),

inally outlined by King and McGuff,¹² provides valid indications for performing biopsies of lesions. It is illogical to continue watching a soft- or hard-tissue lesion grow progressively larger while not recommending definitive diagnostic and therapeutic steps to the patient. Even if such a lesion turns out to be benign, the morbidity resulting from the surgery increases proportionately as the lesion grows larger or encroaches on vital anatomic structures. Any time that improvements in the clinical features of a lesion are not noted or the clinical diagnosis becomes uncertain in the judgment of a reasonable and prudent doctor, courts generally view it as an indication that diagnostic biopsy needs to be performed as soon as possible.¹³

HOW OFTEN SHOULD THE PATIENT BE MONITORED?

As noted above, there are no consistent guidelines in the literature regarding the timing of appointments for re-evaluation of suspicious lesions, with or without histopathologic evaluation. Flexible guidelines can help clinicians make decisions, but decision-making is mostly a matter of reasonable judgment and experience.

The frequency and length of follow-up and management of any pathological condition is influenced by many factors, so only generalized guidelines can be proposed. We strongly emphasize that our recommendations are intended to be neither rigid professional guidelines nor legal standards that apply to all clinical situations. In certain cases, the judgment and experience of the clinician may indicate the need to deviate from these recommendations.

Timetable for follow-up examinations.

Clinicians usually determine the timetable for follow-up examinations once the pathological diagnosis has been established or when the lesion

INDICATIONS FOR BIOPSY.*

dAny persistent pathological condition that cannot be diagnosed clinically, including the following:

dLesions with no identifiable etiology that persist for more than 10 to 14 days, despite local therapy

dAny intrabony lesions that appear to be enlarging

dAny lesion that is felt to have malignant or premalignant characteristics, including the following:

dAny lesion that has grown or is growing rapidly for no obvious reason

dRed, white or pigmented mucosal lesions or combinations of these mucosal lesions for which a cause or diagnosis is not evident

dAny lesion that feels firmly attached or fixed to adjacent structures

dAny unknown lesion in a high-risk area for development of oral cancer (for example, floor of mouth, tongue)

dConfirmation of clinical diagnostic suspicions

dAny lesion that does not respond to routine clinical management, such as antibiotic therapy or endodontic treatment, over a reasonable period

dAny lesion that is a source of extreme concern to the patient (that is, cancerphobia: the patient's fear about a persistent lesion is greater than the concern about undergoing a minor surgical procedure)

* Based on information from King and McGuff.¹²

behaves in a manner that is not anticipated on the basis of the provisional diagnosis. For example, the interval between follow-up appointments might be reduced significantly if clinical signs suddenly change, such as the appearance of previously undetected sensory nerve dysfunction. Guidelines such as these must be weighed against the individual factors presented by the patient and his or her lesion or lesions, as well as the clinician's training and experience, and must be altered whenever indicated by the findings.

Prebiopsy monitoring. We found substantial agreement in the literature that any undiagnosed lesions usually should be followed up for seven to 14 days, with or without local treatment.^{3,12} A study conducted in Ireland indicated that 68.5 percent of dentists referred patients with white lesions within one month of discovery, 80.1 per-

cent referred patients with red lesions within that period, and 89.7 to 91.7 percent referred patients with lumps and ulcers within one month.¹⁵ If the lesion grows, develops alterations in characteristics or does not respond to therapy, then biopsy clearly is indicated.

If the lesion has not disappeared, but has not changed in appearance or surface characteristics during the seven- to 14-day period, then the clinician must decide whether a biopsy should be performed or the lesion merely should be re-evaluated periodically. Clinical experience and advanced training often assist in this decision-making process. Ultimately, the patient must consent to the procedure; therefore, it is incumbent on the clinician to educate him or her about the treatment risks, rationale and alternatives, so that the patient feels part of the decision-making process. However, patients must understand that they share the responsibility involved in a decision not to perform a biopsy of a lesion, and clinicians must make sure that patients are fully informed of the various facets of that decision.

Although some clinicians feel that all lesions should be removed, common sense would seem to indicate that there are some clinical situations in which clinical observation may be preferable. Wright¹⁶ noted that some leukoplakias in lower-risk areas with no histologic evidence of dysplasia may be observed as long as clinicians remember that they still are premalignant lesions that should be followed up as long as they are present. Lesions with mild dysplasia generally are not life-endangering, and some may simply be watched closely. Similar small lesions with mild dysplasia in high-risk sites for the development of oral cancer that are amenable to excision should always be removed. Lesions with moderate-to-severe dysplasia always should be excised.^{16,17} Generally speaking, a decision to perform a biopsy usually is superior to a decision not to perform a biopsy, because biopsy yields a definitive diagnosis, removes the threatening tissues and validates the clinical decision to treat.

Dentists should remember that the responsibility for successful outcome rests substantially in their hands, and many life-endangering conditions initially can masquerade as innocuous clinical lesions. This is especially true of erythroplastic lesions, which frequently harbor neo-

plastic elements despite an innocuous clinical appearance.^{17,18} Biopsy should be avoided only when the procedure would significantly endanger the health or safety of the patient.

Noninvasive screening techniques such as cytologic testing (including brush biopsy) and lesion staining with supravital dyes have many pitfalls and should not be considered as substitutes for biopsy when there is concern about malignancy.^{13,17,19} Cytologic testing should be considered only as a screening adjunct to careful oral examinations.

Monitoring a clinical lesion with a low index of suspicion. If the decision is made not to perform a biopsy of a lesion with a low index of clinical suspicion, a provisional clinical diagnosis should be formulated and entered in the patient's dental record. With the informed consent of the patient, clinicians need to make arrangements for appropriate periodic follow-up to monitor changes in the lesion or adjacent tissues. If the clinician is inexperienced and unsure of the best clinical course, then referral to an oral pathologist, oral and maxillofacial surgeon or other specialist for a second opinion

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In general, and depending on individual findings and circumstances (as discussed above), we recommend that patients be re-examined carefully within one month and then at three, six and 12 months after the initial examination. If significant changes are noted at any of these examinations, a biopsy should be arranged immediately. After one year, most unchanged lesions can be monitored every six months, and after two years most can be monitored semiannually or annually as part of the patient's routine dental examinations. For maximum medicolegal protection, these follow-up guidelines can be printed and given to patients, with a copy inserted into the patient's record. Patient guidelines should include an advisory that the patient contact the dental office if any changes are noted in the area of the lesion before the next scheduled visit.

Monitoring after biopsy. When the histopathologic diagnosis does not yield any suspicion of malignant or premalignant changes, but clinical concerns remain, the dentist and oral pathologist should confer to decide whether it is appropriate to perform another biopsy, remove tissue from another area, remove a larger speci-

men or simply observe the site over time. Inexperienced clinicians tend to place an unwarranted amount of faith in a diagnosis based on biopsy findings.^{12,20} Trott and Morrow²⁰ warned that one never should accept a pathological report at face value, but must interpret it with the clinical impressions in mind. If doubt exists, then a second opinion is recommended.

If there are no suspicious pathological findings and a second biopsy does not seem indicated, this decision should be documented and a plan should be formulated for periodic re-evaluations. The general timetable for follow-up examinations (noted above) still pertains. Patients should be given instructions to contact the dental office if any changes are noted in the area of the lesion before the next scheduled visit. Thorough documentation, including radiographs and photographs when indicated, should be performed at each visit.

Leukoplakia. Areas of leukoplakia are especially troublesome. Approximately 15 to 20 percent of leukoplakias and almost all erythroplakias will exhibit evidence of dysplasia or invasive carcinoma.¹⁶ As the degree of dysplastic change increases, so does the likelihood of malignancy development, especially in certain high-risk areas of the mouth, such as the floor, lower lip, and lateral and ventral surfaces of the tongue. When monitoring leukoplakias, dentists should respond to changes such as the development of redness, ulceration or a pebbled surface morphology by immediately scheduling a second biopsy. Likewise, when any changes are noted in pigmented lesions, clinicians should schedule a follow-up biopsy that includes generous margins.

RECOMMENDATIONS FOR DOCUMENTING CASES

In general, when treating patients with pathological lesions, clinicians must document the cases thoroughly and accurately. In our experience, the guidance given for documentation often is confined to instructions on how to fill out the biopsy submission form, not on how to annotate patients' records. In reviewing pretrial records for litigation for alleged mishandling of pathology cases, we often note that record keeping is less than optimal and there are significant deficiencies in the documentation of intraoffice and interoffice communications. These problems are correctable by proper staff training and by timely referrals and retention of communications be-

tween patients, general dentists and specialists to whom patients are referred.

After performing the oral examination, clinicians must document the findings and include a thorough, annotated medical health history signed by the patient and a thorough initial evaluation note that includes detailed descriptions of the clinical appearance (including radiographs and photographs, as applicable) and location of the lesion or lesions. Follow-up notes should be equally thorough and all notes should be signed or initialed by the dentist.

Reviewing auxiliary staff members' findings. If the initial findings are recorded by an auxiliary staff member (for example, a dental hygienist), it is imperative that the records reflect a subsequent evaluation by the dentist (in addition, the auxiliary staff member must sign or initial any entries he or she makes). It is prudent, and in some states mandatory, that entries by auxiliary staff members be initialed by the doctor, signifying his or her awareness of the contents of the note. If the dentist chooses not to follow up on concerns noted by the hygienist, the record should reflect the rationale for this decision. The results of any diagnostic tests performed, such as pulpal vitality or sensory nerve dysfunction, also should be recorded.

Recording details of lesions. A precise measurement (in millimeters or centimeters) of the dimensions of the lesion is needed. The clinician or staff member can sketch the general shape and appearance of the lesion or lesions at each visit for comparison purposes. These important details are unlikely to be remembered one month or six months in the future.

Obtaining photographs. Clinical photographs are of great value in some cases, especially if taken before a biopsy is performed. If the dental office has a clinical camera, use it. The photographs may be of great value to specialists who subsequently treat the patient and to the oral pathologist. The photographs should be taken from multiple perspectives, especially if taken with a ringlight flash attachment, which tends to obliterate shadows and reduce depth perception.

Differential diagnoses (even if general) and a provisional primary diagnosis should be documented in the patient's record, including a notation regarding the clinician's degree of clinical suspicion (that is, from low to high).

Recording patient discussions. We advise clinicians to include a record of discussions with

the patient concerning alternative courses of action, risks, prognosis and treatment plans, as well as a notation that the patient has given his or her informed consent for these plans. If a patient refuses to follow the dentist's recommended treatment plan, this should be thoroughly documented in the patient's dental record.

Follow-up scheduling. In addition, dentists should maintain a detailed follow-up schedule (such as two months, four months) for monitoring the lesion or lesions. This can be a preprinted form, with the first copy going to the patient and the second copy going into the patient's record. A record of any telephone calls or other discussions with specialists about the case likewise should be kept.

Clinicians should document the patient's next scheduled appointment in the dental record. Although the patient is responsible for keeping appointments, it is best not to rely on him or her to call at some vague future date to make an appointment. Denial is a strong factor in some cases, and patients subconsciously may avoid calling to set up an appointment out of fear.

We recommend that office staff members develop a "tickler" system that allows them to place reminder calls to patients, send written reminders or both before appointments. It is then the responsibility of the patient to keep the appointment. Any missed appointments, patient inquiries, changes of appointment, noncompliance with the treatment plan or after-hours telephone calls should be documented in the patient's record.

If a patient fails to return for follow-up, the dental office should consider sending him or her a reminder (perhaps via registered mail) of the possible consequences of this noncompliance and advise the patient that termination of the professional relationship may result. This must be done carefully, however, to avoid any allegations of patient abandonment.

Conferring with other clinicians. If the dentist seeks a second opinion from a specialist, we believe it should be noted in the patient's record, and copies of any referral letters, electronic mail or evidence of telephone calls between clinicians also should be included. In our opinion, many litigated cases have come down to finger-pointing between generalists who claim to have referred a patient for opinion, biopsy or both and specialists who deny that this was the purpose of the referral.

Obtaining radiographs. Periodically taking

diagnostic radiographs generally is prudent when following up an intrabony lesion or a surface lesion that appears to be just beneath or within the mucosa overlying bone. This helps determine whether the lesion is a mucosal lesion that is eroding bone or a lesion originating in the bone that is eroding to or through the mucosae. We are familiar with several cases in which periodic radiographs were not obtained and the lesion continued to expand internally, while the dentist monitored only the mucosal presentation. Other diagnostic studies, such as magnetic resonance imaging and computed tomography, may be indicated depending on the circumstances of a particular case. The timing of repeated radiographs usually coincides with scheduled follow-up examinations.

DISCUSSION

Several years ago, Trott and Morrow²⁰ stated that only approximately 1 percent of all routine pathological specimens that a pathologist receives from dentists unexpectedly will turn out to be malignant. In their series, only four (13.3 percent) of 30 squamous-cell carcinomas were correctly diagnosed by the original clinician when biopsy was not performed. With that thought in mind, dentists should use utmost caution when deciding to follow up a lesion without an initial diagnostic biopsy. It should be evident to clinicians that the lesion has exhibited no clinical findings suggestive of malignant or premalignant changes.

When considering follow-up of a patient without an initial diagnostic biopsy, dentists must obtain a detailed written history of the patient's habits (such as cheek biting); pertinent risk factors, such as regular exposure to alcoholic beverages and tobacco; and medical status (for example, immunocompromising diseases). The patient must be fully educated about the risk involved in deciding not to undergo a biopsy, and should be given the opportunity to seek a second opinion.

Dentists should be cognizant of clinical changes that might suggest a malignant or premalignant disease. If a cause cannot be identified for a non-healing ulcer, leukoplakia, erythroplakia or a swelling that increases in size, then biopsy generally is mandatory. Likewise, biopsy should be performed on any lesions that produce symptoms or exhibit evidence of growth. Apical and periodontal conditions that do not respond to routine dental treatment should be considered for biopsy. Leuko-



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plakias can be a particular concern, since approximately 80 percent of leukoplakias that undergo biopsy exhibit only hyperkeratosis, acanthosis or both.¹⁶ Clinicians should remember, however, that the absence of dysplasia in a

biopsy specimen does not preclude dysplasia's being present in other areas of the tissues. Even in the absence of dysplasia, these lesions still are considered premalignant, and patients must be reminded of significant risk factors for the development of malignancy, such as continued tobacco use and alcohol intake.

Data show that patients who continue to smoke are more susceptible to formation of new primary tumors.¹⁸ It is reasonable to conclude that this susceptibility to malignant transformation is heightened when the oral mucosa is continuously barraged with carcinogens from tobacco, especially when tobacco use begins early in life. With this in mind, a clinician's index of suspicion should be higher in patients with these risk factors, and patients should be counseled on how to quit their use of tobacco and alcohol. In fact, Pindborg²¹ noted that 60 percent of leukoplakic lesions can be reversed over time with cessation of tobacco use.

CONCLUSIONS

We must stress that these management recommendations should not be construed as rigid clinical or legal guidelines. When faced with an unknown, but benign-appearing, lesion or a histopathologic report that fails to diagnose frank malignancy or premalignancy but suggests a potential for future dysplastic change, dentists have a professional responsibility to their patients to evaluate the lesion closely on an ongoing basis. This demands administrative attention to details

by office staff members, periodic evaluations by the dentist, detailed documentation and timely referral when indicated.

Generally, it is prudent to examine most patients within one month of the initial evaluation, then at three, six and 12 months for the first year after the initial evaluation. If the clinical and radiographic findings remain unchanged, then the period between recall appointments can be lengthened to six months, then 12 months. Patients must be educated about the importance of, and indications for, calling the dental office before their next regular appointment if changes are noted in the area of the lesion or lesions. With additional study of lesion behaviors, these interim recommendations may need to be refined. ■

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This article is informational only and does not constitute legal advice. Dentists must consult with their private attorneys for such advice.

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