

*A Risk Management Newsletter from OMSNIC*

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*In this issue, important trending topics, such as ways you can reduce the incidence of a failure to diagnose claim and steps you can take to prevent fires in the OMS office are covered.*

## Reducing the Incidence of Failure to Diagnose Claims

Colin Bell, DDS, MSD - Patient Safety and Risk Management Committee Member



OMSNIC closed claims data over the past 10 year period reveals that less than 5% of claims and indemnity payments are classified as “failure to diagnose.” Most significant among these claims includes failure to diagnose oral malignant disease, primarily squamous cell carcinoma, as well as infections, osteomyelitis, and fractures. Although these claims represent a small percentage of claims reported to OMSNIC, legitimate failure to diagnose malignant disease matters may result in dire consequences for patients and sizeable costs to adjudicate such claims.

The American Cancer Society estimates that in 2017 approximately 49,670 new cases of oral and oropharyngeal cancer were diagnosed, resulting in more than 9,700 deaths. Approximately 80% of these malignancies were classified as squamous cell carcinoma. The incidence of oral squamous cell carcinoma for lip, gingivae, and floor of the mouth have decreased over the last few decades, mirroring decreases during the same time frame in alcohol and tobacco use. However, rates for diagnosis of new cases of oropharyngeal squamous cell carcinoma, including tongue and soft palate have increased especially in younger Caucasian men and women. Many investigators attribute this increase to more frequent exposure to human papillomavirus (HPV), particularly HPV 16.

*Biopsy and accurate histopathologic diagnosis support a pathway for diagnosis and ultimate management of many suspicious oral lesions.*

Perhaps the most common diagnostic dilemma in failure to diagnose claims the oral and maxillofacial surgeon faces is how to assess and manage white lesions in the oropharynx. These lesions, including leukoplakias, are commonly encountered in daily practice. Most white lesions are benign frictional ketatosis, or lesions that are primarily inflammatory in nature. Leukoplakia is the term used for a white lesion

that is precancerous and is defined by the World Health Organization as “a white plaque of questionable risk having excluded (other) known diseases or disorders that carry no increased risk for cancer.” It is one of several potentially malignant oral lesions including erythroplakia and submucous fibrosis. However, consensus is lacking for management and treatment of leukoplakias, with or without histopathologic evidence of dysplasia.

### Importance of a Biopsy and Follow-Up

Biopsy and accurate histopathologic diagnosis support a pathway for diagnosis and ultimate management of many suspicious oral lesions. Biopsy results that confirm the diagnosis of leukoplakia with dysplasia at the specimen margin may prompt the OMS to re-excise the lesion. A three month follow up is generally considered with dysplastic lesions for an extended period of time to allow prompt treatment should a lesion recur or spread.

Setting up a reliable system helps the practice to verify follow up visits. Adjunctive diagnostic aides may include:

- Vital tissue staining with toluidine blue;
- Brush biopsy examination;
- Autofluorescence techniques;
- Chemofluorescence techniques; and
- Biomarker assessment.

## Reducing the Incidence of Failure to Diagnose Claims

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It is important, however, to consider that the utility of these techniques may not be sufficient for primary diagnosis because they often yield false positive results that may confuse the diagnostic picture.

### Doctor-Patient Communication

Communication is one key element of patient safety and risk management. Communication is critically important in the assessment and management of potentially malignant disease to help avoid a failure or delay in diagnosis that may negatively impact a patient. Effective communication starts with educating the patient about their unique disease process, emphasizing that early diagnosis and treatment is critical to optimize their overall care and reduce any potential untoward results. Each patient must understand active participation in their care is paramount to obtaining the best clinical outcome and that failure to assume responsibility in their care will negatively impact their overall health.

*Effective communication starts with education of the patient about their unique disease process, emphasizing that early diagnosis and treatment is critical to optimize their overall care and reduce any potential untoward results.*

A patient may refuse a biopsy or proposed treatment plan for fear of receiving bad news. Patients who openly and persistently refuse an indicated biopsy may require additional education. All discussions with the patient regarding refusals should be documented. Consider sending a letter summarizing your efforts to the patient. This letter will serve to document how a refusal of treatment could negatively impact the patient's health.

If a patient does proceed with having the biopsy, consider tracking pathology specimens to close the loop on other causes of failure to diagnose claims. Make sure the histopathologic reports are received and communicated to patients and other affiliated health care providers in a timely fashion.

### Conclusion

Each OMS is taught to place the patient first and do everything possible to ensure quality patient care that is safe and effective. The result of this attentive care will hopefully reduce the incidence of failure to diagnose claims. Documentation of this process includes a strong informed consent process, and proper documentation in the patient record of refusals, and follow up efforts. On page 8 you will find a listing of helpful resources OMSNIC offers that can help with documentation of this process.

### References

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## OMSNIC's 30 Year Anniversary

William C. Passolt, CPA - OMSNIC President and CEO



On April 12, 1988, AAOMS Mutual Insurance Company, a Risk Retention Group (as OMSNIC was then known) received regulatory authority to begin issuing policies. Put differently, the Company was officially open for business. This past April, we celebrated OMSNIC's thirtieth anniversary of defending the specialty.

I was reminded at a recent ROAAOMS event that many OMS who started practice years later do not know the history which led to the Company's founding. The short story is OMS had been through a period of staggering rate increases for professional liability insurance – 50% to 100% annually – during the early 1980's. Commercial insurance companies' losses on OMS claims were rising at an unsustainable pace and the companies who even offered OMS coverage were charging exorbitant rates for coverage.

The AAOMS studied the issue and possible solutions, debating the idea of creating an OMS owned and operated insurance company. The Federal government's passage of the Liability Risk Retention Act of 1986, which allowed insurance companies insuring common risks of a defined group to be formed with reduced regulation, provided AAOMS the vehicle it needed. AAOMS Mutual, OMSNIC's former name, was formed under this new law, with initial financial support and capital supplied by AAOMS. The Company eventually paid this financial support and capital back to AAOMS with interest within its first few years of operations.

The Company was formed with the following objectives:

- Provide an aggressive defense of meritless claims or claims with unreasonable demands.
- Provide an affordable and available market for OMS professional liability insurance.
- Develop risk management education that would help OMS avoid claims by providing better patient care or to better protect themselves should they be subject to a claim.
- Accomplish all of these objectives via an OMS owned and operated company, peers providing insurance for their colleagues.

*OMSNIC's long-term success is a continuing reminder of what OMS can do when working together to address the complex matters the specialty often faces.*

The simple premise that OMS could better manage OMS professional liability claims and provide OMS-specific education and resources to minimize claims (all at an affordable cost) has proven effective for thirty years. OMSNIC has a reputation for fighting defensible claims, even when it costs more than simply settling the claims. OMSNIC's patient safety and risk management education and resources have helped reduce the frequency of OMS claims by half since the Company started, thus providing some relief of the threat of litigation to

OMS. This has resulted in insurance rates being less than they were at the Company's formation. All of this was done under the guidance of an active OMS Board of Directors and the additional involvement of many OMS serving on committees, advisory boards, and councils for the company.

Nearly all OMS who were there in 1988 would agree that AAOMS forming OMSNIC was transformative for the specialty. It is therefore fitting that OMSNIC celebrates its 30th anniversary during AAOMS' 100th anniversary. OMSNIC's long-term success is a continuing reminder of what OMS can do when working together to address the complex matters the specialty often faces.

## An OR Fire! Can it Happen to You?

Jeffrey D. Stone, DMD, MD - Patient Safety and Risk Management Committee Member



Even though a fire in the OMS office is a rare occurrence, the consequences of flash fires can be devastating, and even fatal. An OMS office should have a well-conceived plan to address such a fire. We may all be familiar with, and have a protocol for, evacuating our office in the event of a fire in the building; however, the risk of a fire occurring intraoperatively is something we generally do not consider on a daily basis. When it comes to patient safety, OMS are aware of how safety and reliability of office medical equipment is crucial. All surgical equipment should be inspected and calibrated routinely and labeled with the date of inspection and results. Electrical inspections, completed by a qualified individual or your equipment vendors, can help eliminate the chance of an electrical injury or burn to your patients or staff. Many of the operating room fires that have occurred in hospital and office settings involve a head and neck surgical procedure due to the close proximity of oxygen and nitrous oxide to the surgical field.

Fire in the operating room is a recognized concern. Although infrequent, the Emergency Care Research Institute (ECRI) estimates this occurs approximately 200-240 times a year. That is approximately the frequency of other surgical mishaps (e.g. wrong site surgery; retained instruments). It is important for those of us who administer anesthesia in our offices to be aware of, and understand how an OR fire happens, and what we can do to avoid this type of incident from occurring.

### The Fire Triad or Triangle

The basis of a fire occurring is what is known as “The Fire Triangle,” which involves three factors existing at the same time to precipitate an intraoperative fire. The three elements include: an oxidizer (N<sub>2</sub>O/O<sub>2</sub>, supplemental gases (or oxygen alone), an ignition source, and a fuel.



In an OMS practice, common ignition sources may include electrosurgical units, lasers, fiberoptic light sources, and high speed drills; any of which can produce a spark. Fuel sources could be surgical drapes, gauze, towels, gowns, masks, alcohol based skin preps, and even the patient's skin and hair. Being aware of the potential for an OR fire, and eliminating components of the Fire Triangle are key factors in avoiding such an event. With that in mind, recommended preventative measures include:

- Avoid open oxygen delivery systems or supplemental oxygen if the patient can tolerate room air only;

## An OR Fire! Can it Happen to You?

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- Allow prep solutions to dry thoroughly, and avoiding use of excessive prep solutions that could pool around the head and neck area, or saturate drapes or towels;
- Be aware that drapes and towels around the head and neck can trap or absorb oxygen increasing their flammability.
- If a known ignition source is being used, soak the drapes in the area with water; stop the flow of oxygen, N<sub>2</sub>O/O<sub>2</sub> or supplemental gases for a minimum of 1 minute prior to using a potential ignition source; use continuous intraoral suction to remove oxygen-enriched gas as it is exhaled.

### Lasers in Oral and Maxillofacial Surgery

Over the past several years, lasers have become popular in all forms of surgery, including oral and maxillofacial surgery. There are many regulations and standards in place related to laser safety. Specific safety protocols should be established and consistently applied. It is best practice to

*There are many regulations and standards in place related to laser safety. Specific safety protocols should be established and consistently applied.*

designate someone in your office to keep staff education on safety procedures for laser use current. Training may include learning about laser safety mechanisms, emergency stop diagnostic software, system time-outs and fiber detectors. A common type of laser injury occurs when proper eyewear is not worn. Protective eyewear

for the patient can help avoid this type of injury. Eyewear should be stored according to the manufacturer's recommendations. Routine inspection of eyewear is necessary since eyewear can degrade over time if not appropriately cleaned and stored.

### Electrocautery in Oral and Maxillofacial Surgery

In 2015, the Agency for Healthcare Research and Quality (AHRQ) reported that electrocautery was the ignition source for 90% of closed malpractice claims related to OR fires against anesthesiologists between 2000 and 2009. Approximately 83% of these fires occurred while a patient was undergoing sedation with the use of supplemental oxygen in high-risk head, neck, or upper chest procedures. Staff working with the OMS should be educated about steps they can take to stop the supplemental oxygenation when needed. Due to the number of incidents involving hand pieces, bur guard maintenance, laser safety, and electro-cautery devices, patient safety should be a priority.

Should a flash fire occur, act quickly. ECRI's Emergency Procedures Checklist contains three steps to take. These should take no more than a few seconds, and be done in rapid succession:

- 1) Stop the flow of inhaled gases to the patient,
- 2) Remove burning material from or on the patient,
- 3) Care for the patient,
- 4) Extinguish fire with wet towels,
- 5) Check the patient's breathing and control bleeding, and
- 6) Call EMT's and have patient evaluated and treated for degree of burn.



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It is important to be aware of the fire triad and to identify ways to mitigate, or even prevent risks. Recommended additional preventative measures that can be taken to prevent a fire in the OMS office are as follows:

- Train staff on the use of surgical equipment, and follow safety and maintenance guidelines, including how to properly maintain and inspect hand pieces;
- Practice a “Time-Out” before starting any surgical procedure;
- Avoid open oxygen delivery systems when you can and avoid supplemental oxygen if the patient can tolerate room air only;
- Allow prep solutions to dry completely;
- Require that patients have protective eyewear placed as soon as they are seated in the chair;
- Pay close attention to equipment labels and packaging on electrocautery devices;
- Avoid the use of excessive prep solutions which can pool around the head and neck area of the patient;
- Follow the manufacturer’s instructions;
- Develop and implement a system to track maintenance and service inspections;
- Avoid the use of worn or poorly maintained equipment; and
- Report any overheating immediately to the manufacturer and take that equipment or tool out of service until repaired.

### Conclusion

Avoid falling into the trap of telling yourself that this is such an uncommon event, “it could not happen to me.” Be aware of the potential, and take steps to avoid it.

### References

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Anesthesia Patient Safety website, [www.apsf.org/resources/fire-safety](http://www.apsf.org/resources/fire-safety)

American Society of Anesthesiologists <http://www.asahq.org/lifeline/anesthesia%20topics/operating%20room%20fires>

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Mehta, Sonya P. MD, MHS and Domino, Karen B. MD, MPH. April 2015. Fire in the Hole!-An OR Fire. Retrieved from <https://psnet.ahrq.gov/webmm/case/346/fire-in-the-hole-an-or-fire>

## The Importance of a Biopsy Test Log

Suzanne Moy, BSHM, CPHRM - *Patient Safety and Risk Manager*



### How to Access the Related Resources

1. Log on to [www.omsnic.com](http://www.omsnic.com).
2. Click on “Clinical and Office Documents” on the left side of the page.
3. Under the heading “Pathology and Biopsy Documents” you will find the following resources:
  - Biopsy Informed Consent
  - Biopsy Refusal Noncompliance Letter
  - Biopsy Lab Test Log
  - Informed Refusal of Biopsy Form
  - Patient Education Following a Pathological Diagnosis
  - Treatment of Cysts or Tumors Informed Consent

Claims alleging failure to diagnose can often be avoided by thoroughly documenting all follow-up information related to diagnostic reports for biopsies and pathology reports. When sending orders to a lab, multiple people and entities may be involved in the process. In the midst of this “trail”, inconsistencies in the transfer of information to and from the lab can occur. For example, a diagnostic report may not have been seen, reviewed, or acted upon by the lab or the doctor. Without an effective tracking system, the chances of lost or misplaced test results can be greater.

An effective tracking system can be as simple as a log with clear and consistent documentation. OMSNIC offers a “Biopsy Lab Test Log” which you can download from [OMSNIC.com](http://OMSNIC.com). If you are utilizing electronic medical records, you may have a tracking system already built-in. Whether you have paper or electronic records, training your staff on follow-up procedures is important. It may also help to designate a specific employee, and a back-up, who will be responsible for maintaining the log and following up as appropriate.

Whatever system or procedure you choose for your practice, consider the importance of documenting the following elements:

- Legible documentation including PHI ( e.g. patient’s name, DOB, MRN);
- Specific test requested;
- Date ordered;
- Date of your expected follow-up appointment with the patient which can be set up before the patient leaves;
- Date received;
- Doctor’s signature indicating report review;
- Specific actions and recommended treatment;
- Notification of diagnosis/results to the patient;
- Document details of the conversation in the chart; and
- Future appointment dates.

Details of any follow-up conversations with the patient and the doctor and/or staff should be documented in the patients chart with the date and time. Follow-up care is a critical phase of treatment, and documentation of the follow-up with any cancelled or missed appointments is important. All members of the OMS practice team play a significant role in maintaining an efficient system to reduce risks in the practice.



## Chart Now, Not Later

Justina De Grado, JD - Claims Analyst



Timely charting is an important aspect of proper record keeping. Delays in charting require you to recall a specific patient's case from the past, and in the event of a claim, the validity of the record can be called into question by the Plaintiff's attorney. See how a late record entry caused further complications for the insured.

### The Background

A 25 year old woman presented to the OMS office with an infection post-extraction of tooth #32. The insured debrided the area, prescribed an antibiotic, and told the patient to follow-up if the infection did not resolve.

At the time of the visit, the insured drafted a hand-written note that she would later type into her electronic record system. The handwritten notes were typically brief and would be further expanded on later when entered into the electronic system. This particular handwritten note stated that she saw the patient for infection and prescribed an antibiotic. This note was placed in the patient file, but no electronic note was entered that day. This handwritten note did not go into detail about follow-up or discuss the debridement procedure that was done.

About six months after the OMS saw the patient, she received a letter from an attorney. The patient had never returned to the insured's office for further treatment but was eventually hospitalized with osteomyelitis. After suit was filed against the OMS, she reviewed the file and noticed that she did not make an electronic note about the visit. The insured added the electronic note based on her recollection and her handwritten note. The note was dated in the electronic system six months after the last visit. During the deposition of the OMS, the plaintiff's attorney questioned her about this note, including its noticeable late date, and called into question its validity and detail.

### What Happened?

After the deposition of the OMS, one of the allegations made against the insured was that the electronic note was not an accurate representation of what actually happened. The plaintiff's attorney was now able to use the late note as a way to call the OMS' credibility into question, as well as to cast doubt about the medical care that was provided. Without the note, the facts of that visit would come down to the OMS' word against the patient's.

The insured clearly remembered the visit and the treatment that was rendered, but the delayed entry in the electronic system, not made until after the letter from the plaintiff's attorney, made it difficult to rely on the note to support her defense. The case was settled before trial.



### Risk Management Tips:

- Document contemporaneously.
- Avoid short hand charting.
- The best time to document is when the information is fresh in your memory.
- A timely and detailed note on the date of the treatment is an effective way to manage conflicting allegations from a patient.

## OMSGuard Patient Safety and Risk Management Education

A wealth of complimentary education, training, and other custom resources are available. Member policyholders and staff can take online courses or attend live seminars for CE credits and premium discounts. Login to [omsnic.com](http://omsnic.com) to access these resources.

### e-Learning Center

This is a robust [risk management education library](#) that provides OMS and staff with courses on demand that are free of charge and designed to be completed at your own pace. The curriculum covers patient safety and risk management as well as emerging issues. Content is written and presented by OMS and legal and insurance experts well versed in oral and maxillofacial procedures.

**Get CE Credit:** Earn CE credit upon successful completion of any [e-Learning Center](#) course.

### Live Seminars

In a collaborative learning environment, OMSNIC's team of speakers integrates case examples with nonclinical issues commonly seen in OMS claims. Check our [online calendar](#) for an upcoming seminar in your area and registration information. Member policyholders who attend a live seminar earn a renewable 5% risk management premium credit that is applicable for three policy periods.

**Can't Attend a Live Seminar?** RMC 413 - Patient Safety and Risk Management for the Oral and Maxillofacial Surgeon available in the [e-Learning Center](#), is a recorded version of the live seminar. Complete RMC 413 to earn 4 CEs and the 5% premium credit.

### ADA CERP® | Continuing Education Recognition Program

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