

Oral Cancer and the GP dentist: An interview with Ronald C. McGlennen, MD

ORARISK™ HPV
PATIENT REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Doer, Jane P.
Date Of Birth: 01/01/1988
Gender: Female

Ordering Provider

Sample Information
Accession: 8008531
Specimen: Oral Rinse
Collected: 11/28/2009 19:39

Received: 11/30/2009 19:39
Reported: 12/01/2009 21:12
Printed: 12/01/2009 21:12

Result: POSITIVE - HIGH RISK HPV IDENTIFIED 16 18

HPV Type(s) Identified	Patient Risk
Mixed Types	High

Test Information	
Reason for test:	Presence of Lesion
Lesion Size:	40mm x 50mm
Lesion Color:	Red
Lesion Location:	Soft Palate
Additional Clinical Information:	

Type Clinical Significance

16 This HPV Type is classified as being of high risk for the development of cancer.
18 This HPV Type is classified as being of high risk for the development of cancer.

Interpretation:
This sample is positive for the following HPV type(s) (16,18). This HPV infection is considered a high risk for development of dysplasia or neoplasia of the ororo respiratory tract. See comment.

Comment:

- Significance:** HPV of the ororo respiratory tract is caused by person to person contact with implications for the development of cancers such as those involving the oral mucosa, the tonsils and the base of tongue. The diagnosis of dysplasia and cancer are based on the morphologic assessment of a cytology or tissue specimen obtained from biopsy.
- Risk:** The assignment of risk of a given HPV type involves several factors including the time duration of the infection, the patient's hormonal and immune status and whether there are coincident social habits or underlying disease that increase the general risk of malignancy. The HPV type identified in this sample is listed as high risk, meaning that these viruses have been associated with malignant changes in infected cells.
- Consider:** A current recommendation following the result of a high risk HPV infection is close observation and repeat testing for persistent HPV one year (12 months) later.

Methodology: Genomic DNA was extracted from the submitted specimen and amplified by Polymerase Chain Reaction (PCR) using primers specific for the human papilloma virus (HPV) Genome. HPV DNA positive PCR products were subjected to digestion by restriction enzymes. Digested DNA fragments were then separated on a polyacrylamide gel, visualized by aid of ethidium bromide and HPV genotype determined by matching the fragment pattern to that of known HPV restriction fragment patterns.

Disclaimer: 1. OralDNA is not liable for any outcomes arising from clinician's treatment protocols and decisions. Dentists should consult with a periodontist or patient's physician when infections are advanced or as indicated by patient's medical condition. 2. OralDNA is not responsible for inaccurate test results due to poor sample collection. 3. This test was developed and its performance characteristics determined by OralDNA Labs, Inc pursuant to CLIA requirements. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Additional information is available from MyOralDNA.com on:

Patient Communication Sample Office Protocol Using OralDNA

6155779055, Fax: 6156272826 www.oraldna.com

Medical Director Ronald McGlennen, MD

Michael Douglas, oral cancer, and the GP dentist: An interview with Ronald C. McGlennen, MD

by Dr. Joe Blaes

For more on this topic, go to www.dentaleconomics.com and search using the following key words: *Michael Douglas, oral cancer, Dr. Ronald McGlennen, Dr. Joe Blaes.*

This month's interview is with Ron McGlennen, MD, chief medical officer of OralDNA® Labs, Inc., a leading provider of salivary diagnostic tests to the dental profession.

Dr. McGlennen is board-certified in anatomic and clinical pathology, and is also board-certified by the American Board of Medical Genetics, with a specialty in clinical molecular genetics. He is internationally recognized as an expert in molecular biology and genetics.

Dr. Blaes: When Michael Douglas announced on the David Letterman Show that he had Stage IV throat cancer, he received a lot of media attention as one would expect. What does this widespread news coverage mean to the dental professional?

RMcG: One of the results of Mr. Douglas' unfortunate oropharyngeal cancer diagnosis is that more people are now aware of oral cancers, and that this disease does not discriminate between celebrities and regular folks. This heightened awareness and concern has prompted people to make appointments with their dentists and ask specific questions about risk factors, diagnosis, and treatment.

Dr. Blaes: Although Michael Douglas had access to the best medical care available, his tumor was not detected until it reached Stage IV. Why do you think it took so long to diagnose?

RMcG: I cannot provide a definitive answer because I was not part of his clinical team. But the fact that his tumor was at the base of the tongue may have made it difficult to be detected by the naked eye or by using an adjunctive screening device. Other risk assessment tools, such as salivary diagnostic tests, that do not require line-of-sight inspection need to be utilized much earlier. This is especially true when the patient is complaining about persistent symptoms, such as a sore throat, and fits a high-risk profile, such as using tobacco and alcohol.

Dr. Blaes: There has been a fairly common sidebar to this news coverage — the link between oral HPV and oral cancer. Does it surprise you?

RMcG: I am pleasantly surprised that so many reporters did their homework and sought out experts who were able to explain that, although oropharyngeal cancer has been traditionally associated with tobacco use and alcohol, the fastest-growing risk factor for this disease is infection with human papillomavirus (HPV).

Dr. Blaes: The at-risk profile seems to have changed overnight, especially for those who have been practicing dentistry for many years.

RMcG: There are many dentists who may read statistics such as, "Of the 34,000 cases of oropharyngeal cancers diagnosed each year, HPV is now found in up to 50% of them," and say to themselves, "When did this happen?"



Dr. Blaes: Or why did this happen?

RMcG: Exactly! The reason why can be attributed to increased sexual activity with multiple partners at a younger age, and the widespread misperception that oral sex is safe sex.

Dr. Blaes: Are there any differences between HPV-positive and HPV-negative cancers?

RMcG: There are actually two main differences: First, oropharyngeal cancer when caused by HPV has a higher survival rate than cancer caused by tobacco and alcohol use. Second, the oral HPV infection can now be detected long before physical symptoms occur.

Dr. Blaes: Why is the survival rate higher when oropharyngeal cancer is caused by HPV?

RMcG: According to a study published in the June 2010 edition of the *New England Journal of Medicine*, the most important factor is that HPV-positive oropharyngeal squamous-cell carcinomas actually responds more favorably to chemo and radiation treatment modalities. The reason for this may be that HPV-positive tumors have lower levels of a certain growth factor receptor called EGFR.

Dr. Blaes: If Michael Douglas has been given a positive prognosis of an 80% survival rate, is it because his cancer is HPV-related?

RMcG: This has been widely speculated, especially since his cancer is being treated with chemo and radiation therapies. But at this time, it is just the speculation of many medical reporters who are trying to connect the dots.

Michael Douglas, oral cancer, and the GP dentist

Dr. Blaes: Can oral HPV be detected before it progresses into a cancerous tumor?

RMcG: Yes. That capability became reality early this year when OralDNA Labs introduced its OraRiskSM HPV test — a noninvasive, easy-to-use screening tool for identifying the various types and levels of oral HPV infection, especially HPV-16 and HPV-18, the variants most commonly linked to oral cancer.

Dr. Blaes: HPV hasn't been in the headlines this much since the launch of Gardasil[®]. Now the discussion is about the oral variety of the virus. Does this put dentists on the front lines, and are they ready to lead the charge?

RMcG: Dentistry has been gradually evolving into an oral medicine discipline, and these recent developments may help to speed up the process a bit. Dentistry is also evolving from a “disease-oriented” model to a “wellness-oriented model.” This provides an excellent opportunity for all dental professionals to detect disease earlier, determine who is more at risk, and ensure better patient outcomes.

However, this evolution is bringing increased responsibility. Dentists need to step out of their clinical comfort zones, and deal with life and death situations or ask very personal questions.

Dr. Blaes: You mean questions to determine whether or not patients may be at risk for HPV?

RMcG: That's right. Here is a list of questions that a dental clinician would ask a patient to determine whether he or she is a candidate for a salivary oral HPV test:

- Do you have a family history of oral cancer?
- Do you smoke or chew tobacco?
- Do you frequently drink alcoholic beverages?
- Are you sexually active?

The last question is going to have to be rehearsed, along with an explanation of why it is important for the dentist or hygienist to ask. What's more, these questions will probably have to be asked in a private room rather than a multiple-chair operatory setting.

Dr. Blaes: The clipboard with the patient history info may have to be filled out in privacy as well.

RMcG: The last thing you want is for patients to not answer the questions honestly because they think someone may be looking over their shoulder. You may also need to designate a woman member of your dental team to have this discussion with female patients, and a parent needs to be included when talking about Oral HPV with a minor. OralDNA Labs also provides a clinician education kit that includes sample scripts and how to discuss the OraRisk test and its results with a patient.

Dr. Blaes: Speaking of results, what if the lab report comes back positive?

RMcG: If the test comes back positive, but there are no visible lesions, then the dentist should recommend that the test be readministered in a follow-up appointment within the next six months, or based on the practice's existing protocol for oral cancer exams.

Very often the oral HPV infection will be eliminated by the patient's immune system. But if a follow-up test indicates persistent HPV infection, referral to an ENT or oral surgeon is recommended.

If the test comes back positive and there is an oral lesion visible to the naked eye or via an adjunctive screening device, the patient should be referred to an oral surgeon or ENT. OralDNA provides complete referral protocol workflow charts for all possible test result scenarios.

Dr. Blaes: Will salivary diagnostic testing change the business of dentistry?

RMcG: There's no doubt in my mind. First, dentists can take full advantage of advanced salivary diagnostic technology with no capital investment. Salivary diagnostic tests for oral HPV and periodontal disease can easily be incorporated into a patient's six-month or annual hygiene appointment.

What's more, with more than 150,000 practicing general dentists in the U.S., no other dental specialty can screen as many patients and have as great an impact on early detection and improved patient outcomes.

Specialists will benefit from referrals from the front lines, plus they will see patients earlier when their treatment of periodontal disease or oral cancer will result in a greater number of successful outcomes.

I also believe that dentist and hygiene appointments will evolve into “wellness appointments” as more salivary tests are introduced and folded into these regularly scheduled opportunities to see patients. This will elevate the level of importance of these periodic appointments, which may in turn reduce the number of cancellations, and increase patient acceptance of additional diagnostic tests and treatment plans.

The general dentist's stature as a clinician will be elevated as an important part of a patient's diagnostic and wellness management team. Ultimately, salivary diagnostic tests can also improve a dental practice's productivity and boost its bottom line. **DE**

Ron McGlennen, MD, is the chief medical officer of OralDNA Labs, and is board-certified in anatomic and clinical pathology. He is also board-certified by the American Board of Medical Genetics with a specialty in clinical molecular genetics. Dr. McGlennen is internationally recognized as an expert in molecular biology and genetics. He can be contacted at rmcglennen@oraldna.com.



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your patients' total body
health and well-being

OralDNA® Labs

Advancing Patient Wellness Through Salivary Diagnostics

Helping patients fight the battle against existing disease is a noble cause, but imagine if you could help them win the fight even before disease has a chance to take hold. With salivary diagnostic tests from OralDNA® Labs, you now have the ability to learn more about your patients' oral health even before clinical signs and symptoms appear. Our tests are based on a wellness model that strives to keep patients healthy by allowing you to detect disease earlier, determine who is at risk, and put them on a path toward a lifetime of overall health and wellness.

**It's amazing what we can find out from a few drops of saliva.
It's even more amazing what you can do to help patients with that knowledge.**

Learn more about OralDNA® Labs and
salivary diagnostics

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