

**Oral Cancer--Minimal Elements for
Screening, Diagnosis, and Evaluation of Oral Lesions
Office of Oral Health and Center for Cancer Surveillance and Control
Maryland Department of Health and Mental Hygiene
August 2001; Revised July 2005; Revised January 2014**

Major Changes

1. Section I. A., defines oral cancer as being cancer of the mouth and pharynx **in direct field of view or of palpation**. This excludes the base of the tongue and portions of the oropharynx not in direct vision or palpation.
2. Section I. C. includes signs and symptoms of oral cancer.
3. Section II on Risk Factors is expanded to include potentially malignant lesions such as leukoplakia and erythroplakia, personal history of immunosuppression or erosive lichen planus, and other behavioral risk factors such as chewing betel nuts. Epstein Barr virus and herpes simplex virus were removed from the list.
4. Section III on Screening and Risk Reduction no longer recommends routine oral cancer screening. The U.S. Preventive Services Task Force states there is inadequate evidence to state whether oral cancer screening decreases mortality from oral cancer. However two settings may warrant additional consideration: 1) opportunistic screening for oral cancer during routine dental or medical care; and 2) targeted public health screening for high risk populations; e.g., heavy smokers and/or chronic alcohol users.
5. Section V. D. The use of “assist devices” such as the ViziLite-TBlue, VelScope, OraRisk HPV test, etc. are not recommended in oral cancer screening, outside of an IRB approved protocol.
6. Section V. E. The use of the transepithelial brush biopsy is no longer recommended. Use of the transepithelial oral brush biopsy in oral cancer screening should be reserved for situations where the use and results are studied in an IRB-approved protocol. Surgical biopsy should be used for definitive diagnosis of suspected oral cancer lesions.
7. Section VI. Recommendations on Diagnosis and Further Evaluation are under the direction of the patient’s medical case manager and are beyond the scope of this document. Sections on Staging Evaluation, Histologic Classification of Tumors, Staging, and Treatment have been removed from this document.

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These are the current minimal elements to be used by the Oral Cancer Screening Programs subject to any new screening and diagnostic tools that may become available.

I. Definitions for the purposes of the Minimal Elements

- A. **Oral cancer** is defined as cancer of the mouth and pharynx in direct field of view or of palpation including cancer of the lips, anterior 2/3 of the tongue, floor of the mouth, palate, gingiva, alveolar mucosa, buccal mucosa, tonsils, uvula, or salivary glands. (Note this definition omits portions of the oropharynx that are not in the direct field of view or of palpation.)
- B. **Medical Case Manager** is the person who is the medical provider (e.g., oral surgeon, physician, nurse practitioner) who makes medical decisions about the patient and assumes liability for those decisions. The Medical Case Manager may be one provider or several for a single patient depending on the services required.
- C. **Signs and symptoms of oral cancer.** Signs and symptoms of oral cancer include the following list below (modified from www.cancer.gov/cancertopics/wyntk/oral/).¹ Most often, the listed symptoms are not from oral cancer; other health problems can also cause them. Early in the course of the disease, oral cancer is often asymptomatic.
- Patches inside your mouth or on your lips:
 - White patches (leukoplakia) are the most common. White patches sometimes become malignant.
 - Mixed red and white patches (erythroleukoplakia) are more likely than white patches to become malignant.
 - Red patches (erythroplakia) are brightly colored, smooth areas that often become malignant.
 - A sore on your lip or in your mouth that doesn't heal
 - Bleeding in your mouth
 - Loose teeth
 - Difficulty or pain when swallowing
 - Difficulty wearing dentures or denture 'ulcer'
 - A lump in your mouth, neck, or salivary gland
 - An earache that doesn't go away
 - Numbness of lower lip and chin
 - Persistent sore throat
 - Change in voice
- D. **Average risk of oral cancer** includes individuals 18 years and older, without any history of tobacco use and/or regular alcohol use, and without other risk factors listed in Section II, a.—f., below.

E. **Increased risk of oral cancer** includes individuals 18 years and above with any of the risk factors listed in Section II, a.—f., below.

II. Risk factors for oral cancer and actions

Certain relatively uncommon but important clinical situations may warrant increased surveillance as judged by the relevant medical case manager. These include a personal history of prior oral cancers², prior potentially malignant oral lesions (leukoplakia, erythroplakia)¹, immunosuppression from renal transplant or other organ transplant³, erosive lichen planus⁴, and Fanconi anemia⁵.

Behavioral Risk Factors	Actions**
a. Using tobacco (current or past): ¹ 1) Smoking: cigarettes, cigars, pipes, or other methods of smoking 2) Using spit tobacco: chewing tobacco, snuff, or other smokeless tobacco exposure	Avoid tobacco use ⁷
b. Chewing betel nuts ¹	Eliminate chewing betel nuts ⁶
c. Heavy alcohol use ¹	Reduce or eliminate alcohol use ⁶
d. Exposure to direct sunlight (lip cancer only) ¹	Use lip balm with sunscreen to reduce sun exposure of lips ⁶
e. Not eating enough vegetables and fruits may increase the risk of oral cancer, some studies suggest ¹	Diet with fruit and non-starchy vegetables ⁸
f. Having oral human papillomavirus (HPV) infection, particularly HPV type 16 (primarily but not exclusively linked to cancer at base of tongue, back of throat, tonsils, or soft palate) ¹	HPV vaccination is recommended for prevention of cervical, vulvar, vaginal, and anal cancer in females, ages 11 to 26 years, and in males, age 11 to 21 ages. HPV vaccination has not been approved for the prevention of oropharyngeal cancer at this time. ⁹

** There is inadequate evidence to determine whether actions taken to eliminate or reduce the behavioral risk factors above, except the avoidance of tobacco use, will prevent oral cancer. However, the professional opinion of the Medical Advisory Committee supports the Actions listed in b.—f., above.

III. Screening and Risk Reduction

- A. Screening for oral cancer: Opportunistic screening and targeted public health screening. (Professional opinion of Oral Cancer Medical Advisory Committee 2013):

There is inadequate evidence to establish whether screening would result in a decrease in mortality from oral cancer.¹⁰ However, two settings warrant additional consideration:

1. Opportunistic screening for oral cancer:
 - a. In patients reporting for routine *dental* care, screening for oral cancer provided by dentists is one component of the patient evaluation to detect any oral abnormality.¹¹
 - b. Similarly, in patients reporting for routine *medical* examination, screening for oral cancer is one component of the patient evaluation to detect any oral abnormality.
 2. Targeted public health screening for oral cancer: Targeted public health screening may be considered if:
 - a. Screening can occur among people at high risk of oral cancer who are unlikely to have routine dental and medical care (for example, heavy smokers and/or chronic alcohol users), and
 - b. Follow-up for abnormalities detected during screening can be assured.
- B. In settings of opportunistic screening or targeted public health screening for oral cancer (III. A, above): Screen for oral cancer those at average or increased risk.

Actions:

- Perform oral cancer screening examination annually
 - Perioral and intraoral soft tissue exam by visualization and palpation
 - Extraoral exam by visualization and palpation

1. It is possible that those adults with symptoms suggestive of oral cancer may be seen in a screening setting. Although an oral cancer screening exam may be performed, an oral cancer diagnostic exam is needed depending on the degree and duration of symptoms and initial findings of the exam. (The components of a diagnostic exam are beyond the scope of these Minimal Elements).

- C. Educate the general public on risk reduction:

Educate about risk factors and actions (pages 2--3, above). Certain risk factors, such as tobacco use, drinking alcohol, HPV infection, and sun exposure increase the risk of oral cancer. Studies have shown that quitting smoking decreases the risk of developing oral cancer. It may seem that by avoiding drinking alcohol, HPV infection, and sun exposure, the chance of having oral cancer would decrease, but that has not been proven.¹²

- D. Individuals who can perform an oral cancer screening exam:

Dentists, dental hygienists, physicians, physician assistants, and nurse practitioners, with proper training, can all perform an oral cancer exam in Maryland. In the event providers

who cannot make diagnoses (e.g., dental hygienists, physician assistants, and nurse practitioners) discover an oral finding of concern, this finding should be reviewed by appropriately trained dentists or physicians.

E. Training:

Training during college or post graduate school and continuing post graduate education/training on how to conduct an oral cancer screening exam is recommended. Training should be based on standards set forth by the National Institute of Dental and Craniofacial Research:

<http://www.nidcr.nih.gov/OralHealth/Topics/OralCancer/TheOralCancerExam.htm>.

F. Equipment needed to perform an oral cancer screening exam:

Screening can be done in any setting. Equipment should consist of appropriate lighting (flash light or pen light) gauze, gloves, mask, mouth mirror or tongue blade; special chair is optional.

IV. Oral Cancer Screening Examination Result Categories

A. Negative oral cancer screening examination: negative findings on perioral, intraoral, and extraoral examination

B. Oral cancer screening examination—positive for finding suggestive of oral cancer

May include:

Extra-oral examination

- enlarged regional lymph nodes
- facial asymmetry
- parotid mass
- perioral skin discoloration
- other palpable masses

Perioral and Intraoral soft tissue examination

- discoloration
- surface abnormalities
- induration
- ulcerations
- erythroplakia
- leukoplakia
- proliferative verrucous leukoplakia
- erythroleukoplakia
- vascular lesions
- variation in size or texture of or asymmetry in the following areas:
 - lips, labial mucosa, buccal mucosa, gingiva, tongue, floor of the mouth, tonsils, uvula, oropharynx, hard and soft palate

C. Oral cancer screening exam—positive for other findings

May include:

- thyroid gland enlarged or nodular
- gum disease
- tooth decay, abscess, etc.

V. Actions and Follow-Up by Result Category

A. Actions and follow-up of negative oral cancer screening examination

1. Recommend annual oral cancer screening exam as part of routine dental care, physical examination, and/or medical care

B. Actions and follow-up of oral cancer screening examination—positive for finding suggestive of oral cancer

1. For mucosal lesions that appear **cancerous or are large and suspicious for cancer**; non-mucosal lesions; lymph node enlargement; or skin abnormalities:

- Refer for biopsy to grade and stage the lesion or to rule out cancer;
- **Caution: excisional biopsy should only be for small lesions 2-4mm. Do NOT excise large lesions (> 4 mm) because it makes subsequent surgery difficult.**

2. For mucosal lesions that are **small (<2cm)**; or for **innocuous lesions** that are of questionable significance:

- Ask if the patient has noticed the lesion and ask how long it has been present
- Advise to stop smoking, drinking, exposure to sun, etc., that is, remove risk factors)

Minimum follow-up:

- Re-examine in 2-4 weeks
 - Lesion resolves: No treatment; routine oral cancer exam every year
 - Lesion persists:
 - Refer for biopsy (see below);

Optional follow-up strategy:

- Refer for biopsy to grade and stage the lesion or to rule out cancer;
- **Caution: excisional biopsy should only be for small lesions 2-4mm. Do NOT excise larger lesions (> 4mm) because it makes subsequent surgery difficult.**

C. Actions and follow-up of oral cancer screening exam—positive for other findings

- Recommend follow-up by appropriate dental or medical/health care provider, depending on the findings; Recommend annual oral cancer screening exam as part of routine dental and/or medical care

D. Use of "assist devices" such as the ViziLite-TBlue, VelScope, OraRisk HPV Test, etc. in screening of average risk persons, screening of people with increased risk, or for further evaluation of lesions that are of uncertain significance on the exam

- There is insufficient evidence that use of commercial devices for lesion detection that are based on autofluorescence or tissue reflectance enhances visual detection of potentially malignant lesions beyond a conventional visual and tactile examination.¹³
- If a program wishes to use an assist device in the program's oral cancer screening, it should be within a study protocol approved by an IRB. Data from such a study would be a valuable addition to the current literature. (Professional opinion of the Oral Cancer Medical Advisory Committee 2013)

E. Use of Transepithelial Brush Biopsy

- Although transepithelial cytology has validity in identifying disaggregated dysplastic cells, the panel suggests surgical biopsy for definitive diagnosis (Classification: D, ADA). Use of a transepithelial oral brush biopsy in an oral screening program should be reserved for situations where the use and results are studied in an IRB-approved protocol. (Professional opinion of Oral Cancer Medical Advisory Committee 2013)

F. Actions and follow-up of Incisional or Excisional Biopsy—results and their management

- No atypia on biopsy: no treatment; routine oral cancer examination every year or sooner if clinically indicated
- Atypia on biopsy: Re-examine in 2-4 weeks
 - Lesion resolves: No treatment; recommend routine oral cancer examination every year
 - Lesion persists after 2-4 weeks: Re-biopsy (NOT brush biopsy) per Medical Case Manager
- Carcinoma, carcinoma in situ, or other cancer on biopsy
 - Refer for further diagnostic evaluation and/or definitive treatment

G. Actions and follow-up of Transepithelial Brush Biopsy results and their management, if used

- Use of a transepithelial oral brush biopsy should be reserved for situations where the use and results are studied in an IRB-approved protocol. (Professional opinion of Oral Cancer Medical Advisory Committee 2013) In the situation of use in a study protocol, the actions and follow-up of the brush biopsy results would be defined by the approved protocol and are beyond the scope of these Minimal Elements.

H. Follow-up of Symptomatic patients with negative oral cancer exam:

- Symptomatic patients with negative oral cancer examinations require case by case evaluation of the symptoms and risk factors with appropriate referral and reexamination as directed by the Medical Case Manager.

VI. Diagnosis and Further Evaluation

Further diagnostic tests should be directed by the patient's Medical Case Manager. Treatment will be recommended by the medical, dental, and surgical team (Medical Case Manager[s]), on an individual basis.

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