Clinical Practice Guideline: Evaluation of the Neck Mass in Adults Executive Summary

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Abstract
The American Academy of Otolaryngology—Head and Neck Surgery Foundation has published a supplement to this issue of Otolaryngology—Head and Neck Surgery featuring the “Clinical Practice Guideline: Evaluation of the Neck Mass in Adults.” To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 12 recommendations developed emphasize reducing delays in diagnosis of head and neck squamous cell carcinoma; promoting appropriate testing, including imaging, pathologic evaluation, and empiric medical therapies; reducing inappropriate testing; and promoting appropriate physical examination when cancer is suspected.

Keywords
neck mass, squamous cell carcinoma, neck cancer, clinical practice guideline

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Neck masses are common in adults, but often the underlying etiology is not easily identifiable. While infections cause most of the neck masses in children, most persistent neck masses in adults are neoplasms. Malignant neoplasms far exceed any other etiology of adult neck mass.1-3

As used in this guideline, a neck mass is defined as an abnormal lesion (congenital or acquired) that is visible, palpable, or seen on an imaging study. The guideline development group (GDG) further qualified neck masses as any mass below the mandible, above the clavicle, and deep to the skin, although it may involve the overlying skin secondarily. Neck masses may develop from infectious, inflammatory, congenital, traumatic, benign, or malignant neoplastic processes. Importantly, an asymptomatic neck mass may be the initial or only clinically apparent manifestation of head and neck cancer, such as...

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squamous cell carcinoma (HNSCC), lymphoma, or thyroid or salivary gland cancer. Evidence suggests that a neck mass in the adult patient should be considered malignant until proven otherwise.1-8

Timely diagnosis of a neck mass due to metastatic HNSCC is paramount because delayed diagnosis directly affects tumor stage and worsens prognosis.9-11 Unfortunately, despite substantial advances in testing modalities over the last few decades, diagnostic delays are common. Forty years ago, patients with a neck mass experienced an average of a 5- to 6-month delay from the time of initial presentation to the diagnosis of malignancy.12 Today, studies continue to report delays as long as 3 to 6 months.13-15

The epidemiology and clinical presentation of mucosal HNSCC have changed recently. Coupled with the substantial morbidity and mortality of this disease, metastatic mucosal HNSCC is the focus of this guideline. However, a malignant neck mass can result from other disease entities, including lymphoma and skin, thyroid, and salivary gland cancer. The workup outlined in the action statements of this guideline may be applied to any cancer that has metastasized to the neck without an obvious primary.

Mucosal HNSCC may originate in the oral cavity, oropharynx, hypopharynx, nasopharynx, or larynx. Occult metastatic spread from the primary cancer to the regional lymph nodes and continued tumor growth within the lymph nodes result in a neck mass. In 2016, an estimated 62,000 people will be diagnosed with HNSCC.16 The incidence of HNSCC of the oropharynx particularly is on the rise—in part as a consequence of infection with the human papilloma virus (HPV). For these reasons, expediting the diagnosis of HNSCC is the principal quality improvement opportunity of this guideline.

The incidence of HPV-positive HNSCC of the oropharynx has more than doubled, whereas the incidence of HPV-negative cancers has decreased by half.17 The rate of HPV-positive HNSCC of the oropharynx (tonsil and base of tongue) is rising so rapidly that by 2020 the incidence of HPV-positive oropharyngeal cancer is estimated to exceed that of HPV-positive uterine cervical cancer.18,19 Patients affected with HPV-positive oropharyngeal HNSCC often present with neck metastasis without an obvious primary malignancy. Two features of HPV-positive HNSCC may contribute to delayed diagnosis. First, as compared with patients with traditional HNSCC, which is HPV negative, patients with HPV-positive tumors are younger and often lack tobacco and alcohol exposure, the 2 most common classic risk factors. Second, because cervical metastases from HPV-positive HNSCC may be cystic, they are often mistaken for branchial cleft cysts, further contributing to delay in diagnosis.20,21

Currently, there is only 1 evidence-based clinical practice guideline to assist clinicians in evaluating an adult with a neck mass.8 Additionally, much of the available information is fragmented, disorganized, or focused on specific etiologies. In addition, although there is literature related to the diagnostic accuracy of individual tests, there is little guidance about rational sequencing of tests in the course of clinical care. This guideline strives to bring a coherent, evidence-based, multidisciplinary perspective to the evaluation of the neck mass with the intention to facilitate prompt diagnosis and enhance patient outcomes.

Guideline Purpose

The primary purpose of this guideline is to promote the efficient, effective, and accurate diagnostic workup of neck masses to ensure that adults with potentially malignant disease receive prompt diagnosis and intervention to optimize outcomes. Specific goals include reducing delays in diagnosis of HNSCC; promoting appropriate testing, including imaging, pathologic evaluation, and empiric medical therapies; reducing inappropriate testing; and promoting appropriate physical examination when cancer is suspected.

The target patient for this guideline is anyone ≥18 years with a neck mass. The target clinician for this guideline is anyone who may be the first clinician whom a patient with a neck mass encounters. This includes clinicians in primary care, dentistry, and emergency medicine, as well as pathologists and radiologists who have a role in diagnosing neck masses. This guideline does not apply to children.

This guideline addresses the initial broad differential diagnosis of a neck mass in an adult. However, the intention is only to assist the clinician with a basic understanding of the broad array of possible entities. The intention is not to direct management of a neck mass known to originate from thyroid, salivary gland, mandibular, or dental pathology as management recommendations for these etiologies already exist.22,23 This guideline also does not address the subsequent management of specific pathologic entities, as treatment recommendations for benign and malignant neck masses can be found elsewhere.23,24 Instead, this guideline is restricted to addressing the appropriate workup of an adult patient with a neck mass that may be malignant to expedite diagnosis and referral to a head and neck cancer specialist.

The GDG sought to craft a set of actionable statements relevant to diagnostic decisions made by a clinician in the

The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in evaluating neck masses. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and otherwise.1-8

As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and otherwise.1-8

The American Academy of Otolaryngology—Head and Neck Surgery Foundation emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.
workup of an adult patient with a neck mass. Furthermore, where possible, the GDG incorporated evidence to promote high-quality and cost-effective care.

**Methods**

**General Methods**

This guideline was developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm as outlined in the third edition of the American Academy of Otolaryngology—Head and Neck Surgery Foundation’s (AAO-HNSF’s) guideline development manual. The GDG consisted of 21 panel members representing experts in advanced practice nursing, clinical pathology, consumer advocacy, emergency medicine, general practice medicine, general surgery, head and neck surgery and oncology, otolaryngology, oral and maxillofacial surgery, physician assistants, and radiology.

**Literature Search**

The recommendations in this clinical practice guideline are based on systematic reviews identified by a professional information specialist using an explicit search strategy. Additional background evidence included randomized controlled trials (RCTs) and observational studies, as needed, to supplement the systematic reviews or to fill gaps when a review was not available. An information specialist conducted 2 systematic literature searches from December 2015 through February 2016 using a validated filter strategy to identify clinical practice guidelines, systematic reviews, RCTs, and comparative studies. The following search terms were used:


The English-language searches were performed in multiple databases, including PubMed (MEDLINE), EMBASE, CINAHL, Cochrane Library, National Guideline Clearinghouse, NICE UK, and CMA Infobase (Canada). In certain instances, targeted searches for lower-level evidence were performed to address gaps from the systematic searches identified in writing the guideline from April 2016 through November 2016.

1. The initial search for clinical practice guidelines identified 11 guidelines. After removal of duplicates and irrelevant references, the total was 6 guidelines. Quality criteria for including guidelines were (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations. The final data set retained 3 guidelines that met inclusion criteria.

2. The initial search for systematic reviews identified 103 systematic reviews or meta-analyses. After removal of duplicates and irrelevant references, the total was 27 articles. Quality criteria for including reviews were (a) relevance to the guideline topic, (b) clear objective and methodology, (c) explicit search strategy, and (d) valid data extraction methods. The final data set retained was 10 systematic reviews or meta-analyses that met inclusion criteria.

3. The initial search for RCTs identified 20 RCTs. After removal of duplicates and irrelevant references, the total was 14 articles. Quality criteria for including RCTs were (a) relevance to the guideline topic, (b) publication in a peer-reviewed journal, and (c) clear methodology with randomized allocation to treatment groups. The total final data set retained 6 RCTs that met inclusion criteria.

4. The initial search for comparative studies identified 143 studies. After removal of duplicates and...
irrelevant references, the total was 140 articles. The quality criterion for including comparative studies was relevance to the guideline topic. The total final data set retained 51 comparative studies that met inclusion criteria.

In a series of conference calls, the GDG defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in August 2016, the GDG met twice, with in-person meetings following the format previously described and using electronic decision-support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) to facilitate creating actionable recommendations and evidence profiles. Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

AAO-HNSF staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in September 2016 and modified an advanced draft of the guideline.

The final guideline draft underwent extensive external peer review, including a period for open public comment. All comments received were compiled and reviewed by the panel’s chair, and a modified version of the guideline was distributed and approved by the GDG. The recommendations contained in the guideline are based on the best available data published through April 2016. Where data were lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

### Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in Tables 1 and 2.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent practice variation is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their individual patients’ interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.

### Table 1. Strength of Action Terms in Guideline Statements and Implied Levels of Obligation.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Definition</th>
<th>Implied Obligation</th>
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<tbody>
<tr>
<td>Strong recommendation</td>
<td>A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.</td>
<td>Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.</td>
</tr>
<tr>
<td>Recommendation</td>
<td>A recommendation means that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.</td>
<td>Clinicians should also generally follow a recommendation, but should remain alert to new information and sensitive to patient preferences.</td>
</tr>
<tr>
<td>Option</td>
<td>An option means that either the quality of evidence is suspect (grade D) or that well-done studies (grade A, B, or C) show little clear advantage to one approach versus another.</td>
<td>Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.</td>
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*See Table 2 for definitions of evidence grades.*
Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GDG sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant’s previously established “stake” in an issue.

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: a key action statement in bold, followed by the strength of the recommendation in italics. Each key action statement is followed by an “action statement profile” that explicitly states the quality improvement opportunity, aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs, and a benefits-harm assessment. Additionally, there are statements of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in Table 3, and the relationship among the statements is depicted in Figure 1.

The role of patient preferences in making decisions deserves further clarification. The role for patient preference depends on the clinical evidence behind each statement. Statements with clinical evidence that clearly demonstrates a benefit have less of a role for patient preference as compared with statements with a less convincing evidence base. Although some statements may have little room for patient preference, clinicians should provide patients with clear and comprehensible information to explain the clinician’s

<p>| Table 2. Aggregate Grades of Evidence by Question Type. |
|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|</p>
<table>
<thead>
<tr>
<th><strong>Grade</strong></th>
<th><strong>CEBM Level</strong></th>
<th><strong>Treatment</strong></th>
<th><strong>Harm</strong></th>
<th><strong>Diagnosis</strong></th>
<th><strong>Prognosis</strong></th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>Systematic review(^b) of randomized trials</td>
<td>Systematic review(^b) of randomized trials, nested case-control studies, or observational studies with dramatic effect(^b)</td>
<td>Systematic review(^b) of cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Systematic review(^b) of inception cohort studies(^c)</td>
</tr>
<tr>
<td>B</td>
<td>2</td>
<td>Randomized trials, or observational studies with dramatic effects or highly consistent evidence</td>
<td>Randomized trials, or observational studies with dramatic effects or highly consistent evidence</td>
<td>Cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Inception cohort studies(^c)</td>
</tr>
<tr>
<td>C</td>
<td>3-4</td>
<td>Nonrandomized or historically controlled studies, including case-control and observational studies</td>
<td>Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series, case-control, or historically controlled studies</td>
<td>Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards</td>
<td>Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study</td>
</tr>
<tr>
<td>D</td>
<td>5</td>
<td>Case reports, mechanism-based reasoning, or reasoning from first principles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>N/A</td>
<td>Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm</td>
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</table>

Abbreviations: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable.

\(^a\)Adapted from Howick and coworkers.\(^{33}\)

\(^b\)A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

\(^c\)A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.
Table 3. Summary of Guideline Key Action Statements.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Action</th>
<th>Strength</th>
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<tbody>
<tr>
<td>1. Avoidance of antibiotic therapy</td>
<td>Clinicians should not routinely prescribe antibiotic therapy for patients with a neck mass unless there are signs and symptoms of bacterial infection.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>2a. Stand-alone suspicious history</td>
<td>Clinicians should identify patients with a neck mass who are at increased risk for malignancy because the patient lacks a history of infectious etiology and the mass has been present for ≥2 weeks without significant fluctuation, or the mass is of uncertain duration.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>2b. Stand-alone suspicious physical examination</td>
<td>Clinicians should identify patients with a neck mass who are at increased risk for malignancy based on ≥1 of these physical examination characteristics: fixation to adjacent tissues, firm consistency, size &gt;1.5 cm, and/or ulceration of overlying skin.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>2c. Additional suspicious signs and symptoms</td>
<td>Clinicians should conduct an initial history and physical examination for adults with a neck mass to identify those patients with other suspicious findings that represent an increased risk for malignancy.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>3. Follow-up of the patient not at increased risk</td>
<td>For patients with a neck mass who are not at increased risk for malignancy, clinicians or their designees should advise patients of criteria that would trigger the need for additional evaluation. Clinicians or their designees should also document a plan for follow-up to assess resolution or final diagnosis.</td>
<td>Recommendation</td>
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<tr>
<td>4. Patient education</td>
<td>For patients with a neck mass who are deemed at increased risk for malignancy, clinicians or their designees should explain to the patient the significance of being at increased risk and explain any recommended diagnostic tests.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>5. Targeted physical examination</td>
<td>Clinicians should perform, or refer the patient to a clinician who can perform, a targeted physical examination (including visualizing the mucosa of the larynx, base of tongue, and pharynx) for patients with a neck mass deemed at increased risk for malignancy.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>6. Imaging</td>
<td>Clinicians should order neck computed tomography (or magnetic resonance imaging) with contrast for patients with a neck mass deemed at increased risk for malignancy.</td>
<td>Strong recommendation</td>
</tr>
<tr>
<td>7. Fine-needle aspiration (FNA)</td>
<td>Clinicians should perform FNA instead of open biopsy, or refer the patient to someone who can perform FNA, for patients with a neck mass deemed at increased risk for malignancy when the diagnosis of the neck mass remains uncertain.</td>
<td>Strong recommendation</td>
</tr>
<tr>
<td>8. Cystic masses</td>
<td>For patients with a neck mass deemed at increased risk for malignancy, clinicians should continue evaluation of patients with a cystic neck mass, as determined by FNA or imaging studies, until a diagnosis is obtained and should not assume the mass is benign.</td>
<td>Recommendation</td>
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<tr>
<td>9. Ancillary tests</td>
<td>Clinicians should obtain additional ancillary tests based on the patient’s history and physical examination when a patient with a neck mass is at increased risk for malignancy and/or does not have a diagnosis after FNA and imaging.</td>
<td>Recommendation</td>
</tr>
<tr>
<td>10. Examination under anesthesia of the upper aerodigestive tract before open biopsy</td>
<td>Clinicians should recommend examination of the upper aerodigestive tract under anesthesia, before open biopsy, for patients with a neck mass who are at increased risk for malignancy and without a diagnosis or primary site identified, with FNA, imaging, and/or ancillary tests.</td>
<td>Recommendation</td>
</tr>
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</table>
recommendation to facilitate patient understanding and informed decision making. In cases where evidence is weak or benefits unclear, shared decision making—where the management decision is made by a collaborative effort between the clinician and an informed patient—is extremely useful. Factors related to patient preference include (but are not limited to) absolute benefits (number needed to treat), adverse effects (number needed to harm), quality of life, cost of
drugs or procedures, and frequency and duration of treatment. Certain, less tangible factors should be considered, such as religious and/or cultural beliefs and patients’ social situations.

**STATEMENT 1. AVOIDANCE OF ANTIBIOTIC THERAPY:** Clinicians should not routinely prescribe antibiotic therapy for patients with a neck mass unless there are signs and symptoms of bacterial infection. **Recommendation based on observational studies with a preponderance of benefits over harm.**

**Action Statement Profile**

- **Quality improvement opportunity:** Avoid routine treatment with antibiotics, which may be inappropriate or ineffective treatment for a neck mass, thus leading to delayed diagnosis of malignancy or other serious illness. (National Quality Strategy domains: safety, promoting effective treatment, affordable quality care)
- **Aggregate evidence quality:** Grade C, based on observational studies
- **Level of confidence in evidence:** Medium
- **Benefits:** Avoid delay in diagnosis of malignancy, promote judicious antibiotic therapy, limit bacterial resistance, reduce antibiotic adverse effects, reduced cost
- **Risks, harms, costs:** Under treatment of a missed bacterial infection
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Perception by GDG that antibiotics are common for noninfectious neck masses, delaying diagnosis and/or referral. Further perception that physical examination is the primary determinant of an infectious cause of a neck mass, and history is a secondary determinant.
- **Intentional vagueness:** None
- **Role of patient preferences:** None
- **Exceptions:** None
- **Policy level:** Recommendation
- **Differences of opinion:** None

**STATEMENT 2a. STAND-ALONE SUSPICIOUS HISTORY:** Clinicians should identify patients with a neck mass who are at increased risk for malignancy when the patient lacks a history of infectious etiology and the mass has been present for ≥2 weeks without significant fluctuation, or the mass is of uncertain duration. **Recommendation based on observational studies with a preponderance of benefits over harm.**

**Action Statement Profile**

- **Quality improvement opportunity:** To use simple questions to identify patients at increased risk for malignancy based on specific historical features (Table 4). (National Quality Strategy domains: safety, promoting effective prevention/treatment)
- **Aggregate evidence quality:** Grade C, based on observational studies
- **Level of confidence in evidence:** Medium
- **Benefits:** Improve outcomes through earlier diagnosis, identify patients with an earlier stage of disease, prioritize testing for high-risk patients, potentially reduce risk of distant metastases through earlier cancer identification, provide psychological benefit through timely evaluation, facilitate further care
- **Risks, harms, costs:** False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** The risk of missing or delaying diagnosis of a malignancy in a patient who is at increased risk is more important than false-positive clinical diagnosis in a patient with nonmalignant disease. Assumption by the GDG that early identification of patients at increased risk with focused questions can improve outcomes, despite any direct clinical evidence to substantiate this assumption.
- **Intentional vagueness:** None
- **Role of patient preferences:** None
- **Exceptions:** None
- **Policy level:** Recommendation
- **Differences of opinion:** None

**STATEMENT 2b. STAND-ALONE SUSPICIOUS PHYSICAL EXAMINATION:** Clinicians should identify patients with a neck mass who are at increased risk for malignancy based on ≥1 of these physical examination characteristics: fixation to adjacent tissues, firm consistency, size >1.5 cm, and/or ulceration of overlying skin. **Recommendation based on observational studies with a preponderance of benefits over harm.**

**Action Statement Profile**

- **Quality improvement opportunity:** To identify patients at increased risk for malignancy because of specific features on physical examination (Table 4). (National Quality Strategy domains: safety, promoting effective prevention/treatment)
- **Aggregate evidence quality:** Grade C, based on observational studies
- **Level of confidence in evidence:** Medium
- **Benefits:** Improve outcomes through earlier diagnosis, identify patients with earlier stage of disease, prioritize testing for patients at increased risk, potentially reduce risk of distant metastases through earlier cancer identification, psychological benefit of timely evaluation, facilitate further care
- **Risks, harms, costs:** False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Rationale</th>
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<tbody>
<tr>
<td>1. Absence of infectious etiology</td>
<td>Absence of recent infection makes infection an unlikely etiology for the neck mass.</td>
</tr>
<tr>
<td>2. Mass present ≥2 weeks or of uncertain duration</td>
<td>A persistent mass is more likely to be malignant</td>
</tr>
<tr>
<td>3. Reduced mobility of neck mass</td>
<td>Metastatic cancer may violate the lymph node capsule and directly invade adjacent structures.</td>
</tr>
<tr>
<td>4. Firm texture of mass</td>
<td>A malignant lymph node is often firm due to the absence of tissue edema. A neck mass may be soft due to its fluid content, and while this sometimes is due to a benign cystic mass, fluid-filled cystic masses may also be malignant. An infectious lymph node may be soft due to tissue edema.</td>
</tr>
<tr>
<td>5. Neck mass size &gt;1.5 cm</td>
<td>Lymph node metastases results in nodal enlargement.</td>
</tr>
<tr>
<td>6. Ulceration of skin overlying the neck mass</td>
<td>Metastatic cancer may break through the capsule of the lymph node and directly invade and necrose the skin. Alternatively, the ulceration overlying a neck mass may indicate a cutaneous malignancy with direct extension into the neck.</td>
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</table>

**Additional characteristics of history and physical examination suspicious for malignancy**

| 1. Age >40 years | Older age is associated with greater risk of HNSCC—particularly in patients with non-HPV related disease |
| 2. Tobacco and alcohol use | Tobacco and alcohol are synergistic risk factors for HNSCC |
| 3. Pharyngitis | “Sore throat” or throat pain may indicate mucosal ulceration or mass |
| 4. Dysphagia | Difficult swallowing may indicate ulceration, mass, or dysfunction of the aerodigestive system |
| 5. Otalgia ipsilateral to the neck mass | Otalgia, with normal ear examination, may represent referred pain from the pharynx. Unilateral serous otitis media may result from eustachian tube obstruction by a nasopharyngeal malignancy |
| 6. Oral cavity or oropharyngeal ulcer | Visible ulceration of mass, tenderness to palpation, or decreased tongue mobility may indicate a malignancy |
| 7. Recent voice change | May indicate a malignancy of the laryngeal or pharyngeal structures |
| 8. Recent hearing loss ipsilateral to the neck mass | May indicate a nasopharyngeal malignancy with unilateral middle ear effusion |
| 9. Nasal obstruction and epistaxis ipsilateral to the neck mass | May indicate an ulcerated malignancy in the nose or nasopharynx |
| 10. Unexplained weight loss | Cachexia is common in cancer patients. Head and neck cancer in particular may cause difficulty swallowing and cause wasting simply from inadequate nutrition. |
| 11. History of treatment for head and neck malignancy including skin, salivary gland, or aerodigestive sites | Prior head and neck malignancy places a patient at risk for local or regional (nodal) recurrence or a second malignancy. Patients with prior radiation treatment are at risk for a secondary neoplasm decades later. |
| 12. Nontender neck mass | An infectious or inflammatory neck mass may be painful or tender. A nontender mass is less likely infection or inflammation and more likely neoplastic. |
| 13. Tonsil asymmetry | May indicate a malignancy within the larger tonsil |
| 14. Skin lesions (face, neck, scalp included) | Cutaneous malignancy can metastasize to the cervical lymph nodes |

**Abbreviations:** HNSCC, head and neck squamous cell carcinoma; HPV, human papilloma virus.
STATEMENT 2c. ADDITIONAL SUSPICIOUS SIGNS AND SYMPTOMS: Clinicians should conduct an initial history and physical examination for all adults with a neck mass to identify those patients with an increased risk for malignancy. Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

- Quality improvement opportunity: This statement moves beyond the previously noted stand-alone suspicious findings (lack of infectious etiology, ≥2-week duration of the mass, reduced mobility, firm texture, size >1.5 cm, ulceration) by using the initial history and examination to identify patients who have signs and symptoms that place them at increased risk of malignancy (Table 4). (National Quality Strategy domains: safety, promoting effective prevention/treatments)
- Aggregate evidence quality: Grade C, based on case series
- Level of confidence in evidence: Medium
- Benefits: Improve outcomes through earlier diagnosis, identify patients with earlier stage of disease, prioritize testing for increased-risk patients, potentially reduce risk of distant metastases through earlier cancer identification, psychological benefit of timely evaluation, facilitate further care
- Risks, harms, costs: False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: The risk of missing or delaying diagnosis of malignancy in an increased risk patient is more important than potentially misclassifying patients with nonmalignant disease. Assumption by the GDG that early identification of at-risk status with the initial history and physical examination can improve outcomes. Assumption by the GDG that the listed signs and symptoms can predict risk of cancer above and beyond lack of infectious etiology, ≥2-week duration of mass, reduced mobility, firm texture, size >1.5 cm, ulceration.
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 3. FOLLOW-UP OF PATIENT NOT AT INCREASED RISK: For patients with a neck mass who are not at increased risk for malignancy, clinicians or their designees should advise patients of criteria that would trigger the need for additional evaluation. Clinicians or their designees should also document a plan for follow-up to assess resolution or final diagnosis. Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

- Quality improvement opportunity: Promote follow-up and engage patients in their care for better outcomes. (National Quality Strategy domains: engaging patients, effective prevention/treatment)
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: Medium
- Benefits: Avoid false-negative diagnosis based on initial assessment, promote follow-up to ensure resolution of benign lesions and detect malignant masses, promote more timely diagnosis if the mass fails to resolve as expected, educate and empower patients, and promote shared decision making (Table 5).
- Risks, harms, costs: Administrative burden for the clinician, health care cost of follow-up assessments
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception by the GDG that despite its importance, patients with neck masses receive inconsistent follow-up
- Intentional vagueness: The timing and method of follow-up is not specified
- Role of patient preferences: Moderate regarding the method of follow-up
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 4. PATIENT EDUCATION: For patients with a neck mass who are deemed at increased risk for malignancy, clinicians or their designees should explain to the patient the significance of being at increased risk and explain any recommended diagnostic tests. Recommendation based on observational studies with preponderance of benefits over harms.

Action Statement Profile

- Quality improvement opportunity: (National Quality Strategy domains: safety, effective treatment)
- Aggregate evidence quality: Grade C, observational studies of the utility of diagnostic tests and imaging studies to assist with diagnosis of neck mass
- Level of confidence in evidence: Medium
- Benefits: Improve understanding of the risk of malignancy in a neck mass as well as understanding of the
need for targeted examination and tests/imaging, engage patients, establish expectations (Table 6)

- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 5. TARGETED PHYSICAL EXAMINATION:
Clinicians should perform, or refer the patient to a clinician who can perform, a targeted physical examination (including visualizing the mucosa of the larynx, base of tongue, and pharynx) for patients with a neck mass deemed at increased risk for malignancy. Recommendation based on grade C aggregate evidence (observational studies) with a preponderance of benefit over harm.

Action Statement Profile
- Quality improvement opportunity: To encourage the use of a complete examination of the neck and the mucosal surfaces of the aerodigestive tract (Table 7). (National Quality Strategy domains: safety, effective treatment)
- Aggregate evidence quality: Grade C observational studies
- Level of confidence in evidence: High
- Benefits: Identification of a primary source of neck mass or malignancy, focus and prioritize subsequent diagnostic tests, ensure that the patient has a full examination of mucosal surfaces by someone with the necessary diagnostic skills and/or equipment
- Risks, harms, costs: Cost of visit, cost and risks of diagnostic tests, detection of incidental lesions, false-positive diagnosis, discomfort (e.g., laryngoscopy)
- Benefit-harm assessment: Preponderance of benefit over harm

What does it mean that I have a neck mass at increased risk for malignancy?
The mass in your neck may indicate a serious medical problem. It does not mean that you have cancer, but it does mean that you need
more evaluation to make a diagnosis. Common symptoms in patients with a neck mass at increased risk for malignancy include
- The mass lasts longer than 2-3 weeks
- Voice change
- Trouble or pain with swallowing
- Trouble hearing or ear pain on the same side as the neck mass
- Sore throat
- Unexplained weight loss
- Fever >101°F

What do I do next?
Your provider will ask about medical history and examine your head and neck. Your provider may order tests or refer you to a specialist.

How urgently should I be evaluated?
Your provider will want to make sure you have a thorough evaluation, testing, and follow-up within a short period of time. It is important
that you discuss this timeline with your provider and make sure that there is a plan for follow-up after testing. It is important for you to
follow this neck mass until it goes away or until you have a diagnosis.

What questions may my doctor ask?
- When did you first notice the lump? Has it grown?
- Have you had a recent illness?
- Do you have any trouble with eating, talking, swallowing, or hearing?
- Any sore spots in your mouth or throat?
- Do you have any sore or growing spots on your scalp, neck, or face?
- Have you lost weight?
- Are citrus fruits or tomatoes painful to eat?
- Do you have ear pain or sore throats that do not go away?
- Has your voice been hoarse?
- Have you coughed up any blood?
- Do you currently smoke, or do you have a smoking history? How much? How long?
- Do you drink alcohol, or do you have a history of drinking alcohol? How much? How long?
- Do you have a history of head and neck cancer?
- Any radiation exposure to your head or neck?
- Do you have any family history of head and neck cancer?

How will the provider examine my mouth and throat?
The provider will look in your mouth and throat with a bright light. If you wear dentures, you will need to remove them. The provider may
use gauze to hold your tongue and feel the surfaces of the mouth, tongue, tonsils, or the back of your tongue.
The provider may use a small mirror in your mouth to see the voice box. If a “scope” is needed, the provider may first numb the nose and
throat. The provider will then place a small tube in your nose and use a camera to examine your throat. You may have mild discomfort.

What is a computerized tomography (CT) scan?
A CT scan is a series of x-rays that give more detail than regular x-rays. CT scan pictures show soft tissue and bones. The CT machine
looks like a large donut that your head, neck, and chest will go through. Patients without an allergy to contrast will need an IV—that is, a
needle inserted into a vein—for contrast to enhance the pictures.
Risks include
1. Contrast allergy
2. Discomfort with IV placement
3. Patients with claustrophobia have minimal anxiety during this brief scan (3-5 minutes).
4. A CT scan uses radiation—about as much as 150 chest x-rays.

What is a magnetic resonance imaging (MRI) scan?
An MRI scan creates pictures of the soft tissue but not the bones. An MRI does not use radiation; it uses very strong magnets. The MRI
machine looks like a narrow tube that your head, neck, and chest will go inside. You will need an IV for contrast to enhance the pictures.
If you have any metal or implants in your body, you may not be able to have an MRI. You must discuss this with your provider.
Risks include
1. IV contrast allergy
2. Discomfort with IV placement
3. Patients with claustrophobia may be very anxious with this lengthy scan (45-60 minutes). Your provider may provide a sedative pill.

What is a fine-needle aspiration (FNA)?
An FNA uses a small needle stuck into the mass to get a tissue sample.
Risks include
1. Discomfort from needle stick
2. Infection
3. Bruising
4. Bleeding
5. Not enough tissue for a diagnosis—repeat procedure
Table 7. Essential Components of a Targeted Physical Examination in a Patient at Increased Risk for Head and Neck Malignancy.

<table>
<thead>
<tr>
<th>Anatomic Site</th>
<th>Examination Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin and scalp</td>
<td>May reveal a cutaneous malignancy</td>
</tr>
<tr>
<td>Otoscopy</td>
<td>Unilateral serous otitis media may suggest a nasopharyngeal malignancy</td>
</tr>
<tr>
<td>Cranial nerves</td>
<td>Itemized assessment of ocular motility, facial sensation and movement, hearing, palate elevation, presence of gag reflex, vocal fold movement, tongue mobility, and shoulder elevation</td>
</tr>
<tr>
<td>Oral cavity</td>
<td>Visual and digital examination of ventral and lateral surfaces of oral tongue and floor of mouth</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>Visual examination of soft palate, tonsillar fossae, and posterior wall. Palpation of the tongue base and tonsillar fossae</td>
</tr>
<tr>
<td>Nasal cavity</td>
<td>Visual examination of the septum, floor, and turbinates</td>
</tr>
<tr>
<td>Nasopharynx</td>
<td>Visual examination of the eustachian tube orifices, superior and posterior walls</td>
</tr>
<tr>
<td>Hypopharynx</td>
<td>Visual examination of pyriform sinuses and posterior pharyngeal wall</td>
</tr>
<tr>
<td>Larynx</td>
<td>Visual examination of the epiglottis, vocal folds, and subglottis</td>
</tr>
<tr>
<td>Neck</td>
<td>Assessment of the pyriform sinuses and posterior pharyngeal wall</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>Palpation of the neck mass firmness, size, fixation, location, and presence of additional lymphadenopathy. Bimanual palpation of the floor of mouth and entire neck</td>
</tr>
<tr>
<td>Thyroid gland</td>
<td>Palpation to assess for mass</td>
</tr>
</tbody>
</table>

- **Value judgments**: Consensus by the GDG that imaging is not a substitute for the additional information obtained by an examination that includes complete examination of the mucosal surfaces
- **Intentional vagueness**: The method (mirror or endoscope) of examination is at the discretion of the clinician, as is the decision to refer the patient to another clinician if one is unable to visualize the pharynx, base of tongue, and larynx.
- **Role of patient preferences**: Small to none; patient may decline examination
- **Exceptions**: None
- **Policy level**: Recommendation
- **Differences of opinion**: None

**STATEMENT 6. IMAGING**: Clinicians should order neck computed tomography (CT; or magnetic resonance imaging [MRI]) with contrast for patients with a neck mass deemed at increased risk for malignancy. *Strong recommendation based on RCTs.*

**Action Statement Profile**

- **Quality improvement opportunity**: To promote timely and effective imaging assessment of a neck mass in patients deemed at risk for malignancy
- **Aggregate evidence quality**: Grade B, RCTs, consistent evidence from observational studies
- **Level of confidence in evidence**: High
- **Benefits**: Ensure that when imaging is ordered, the right test is selected and that contrast is given, distinguish malignant from benign masses, plan for fine-needle aspiration (FNA) or biopsy, define extent of disease to facilitate staging, detect occult disease, guide treatment decisions, further testing and referral
- **Risks, harms, costs**: Radiation (CT), contrast adverse reactions, anxiety, claustrophobia, cost, incidental findings, false positives, false negatives
- **Benefit-harm assessment**: Preponderance of benefit over harm
- **Value judgments**: None
- **Intentional vagueness**: The clinician may choose whether to order CT or MRI based on the specific clinical situation.
- **Role of patient preferences**: Small role. Claustrophobic patients may prefer CT over MRI. MRI may be preferable if radiation exposure is a concern.
- **Exceptions**: Imaging recommendations may be altered in pregnancy. The protocol for contrast administration may be altered in the setting of contrast allergy or renal insufficiency.
- **Policy level**: Strong recommendation
- **Differences of opinion**: None

**STATEMENT 7. FINE-NEEDLE ASPIRATION**: Clinicians should perform FNA instead of open biopsy, or refer the patient to someone who can perform FNA, for patients with a neck mass deemed at increased risk for malignancy when the diagnosis of the neck mass remains uncertain. *Strong recommendation based on systematic reviews with a consistent reference standard.*

**Action Statement Profile**

- **Quality improvement opportunity**: Avoid unnecessary open biopsy with its associated complications and promote timely FNA as the initial pathologic test for a patient with a neck mass at increased risk of malignancy *(Table 8)*. (National Quality Strategy domains: safety, effective treatment)
- **Aggregate evidence quality**: Grade A, systematic reviews with a consistent reference standard
- **Level of confidence in evidence**: High
- **Benefits**: Rapid, cost-effective test with high sensitivity and specificity for diagnosis, minimal
Table 8. Patient Handout: Neck Mass Biopsy—What Should the Adult Patient Expect?

<table>
<thead>
<tr>
<th>What is a biopsy?</th>
<th>A biopsy involves taking a sample of tissue from the neck mass. This sample of tissue is looked at under the microscope by a pathologist (a specialized doctor) to make a diagnosis. A biopsy is a common test to check for cancer. There are different types of biopsies that can be done. The type of biopsy performed is according to your history and the location of your mass.</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the different types of biopsies?</td>
<td></td>
</tr>
<tr>
<td>1. Fine-needle aspiration (FNA)</td>
<td>An FNA is the best initial test to diagnose a neck mass. A small needle is put into the mass, and tissue is pulled out. An FNA is often done in your doctor’s office. It is well tolerated by most patients. Risks include • Discomfort • Bruising • Infection • Not getting enough tissue for a diagnosis</td>
</tr>
<tr>
<td>2. Core biopsy</td>
<td>A core biopsy is another way to diagnose a neck mass. A core biopsy may be done instead of or after an FNA. A core biopsy uses a slightly larger needle and gets a larger piece of tissue. It is well tolerated and has a low risk of complications. Risks include • Bleeding • Bruising • Discomfort • Infection • Not getting enough tissue for diagnosis</td>
</tr>
<tr>
<td>3. Open biopsy</td>
<td>An open biopsy is another way to diagnose a neck mass. It is a more invasive procedure. Open biopsy is done by a surgeon in the operating room, and you will need anesthesia. An open biopsy may remove only a portion of the mass or the whole mass. Because open biopsies are more invasive, there is a higher risk for complications. Risks include • Complications of anesthesia • Infection • Bleeding • Discomfort • Scarring • Nerve injury (numbness, paralysis)</td>
</tr>
</tbody>
</table>

What should I do to prepare for a biopsy? If you need an open biopsy, your provider will tell you how to prepare. For any biopsy, let your provider know if you take blood thinners or have bleeding problems.

When should I get my results? Your medical provider should call you or set up a follow-up appointment within 1 week of your biopsy. If you do not get your results after 1 week, you should call your medical provider.

discomfort, low risk of seeding malignancy, does not affect imaging results, can prioritize further imaging or workup

- Risks, harms, costs: Discomfort, direct cost, risk of nondiagnostic or indeterminate test results
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception by the GDG that some patients undergo inappropriate open biopsy prior to attempted FNA. The GDG also noted that some patients experience unwarranted delay prior to tissue biopsy
- Intentional vagueness: There are a variety of techniques, operators, and settings in which neck mass FNA may be performed; these choices are left to the discretion of the clinician and patient.

- Role of patient preferences: None
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 8. CYSTIC MASSES: For patients with a neck mass deemed at increased risk for malignancy, clinicians should continue evaluation of patients with a cystic neck mass, as determined by FNA or imaging studies, until a diagnosis is obtained and should not assume that the mass is benign. Recommendation based on observational studies with a preponderance of benefit over harm.
Table 9. Patient Handout: Examination Under Anesthesia—What Should the Adult Patient Expect?

**What is examination (endoscopy) under anesthesia?**
Examination under anesthesia is performed by a surgeon to evaluate the back of your throat, voice box, the back of your nose, upper trachea (breathing tube), and upper esophagus (swallowing tube).

**Why do I need an examination under anesthesia?**
This test allows a complete evaluation of the back of your nose and throat, your voice box, the windpipe, and esophagus (swallowing tube). If your doctor sees an area of concern, he or she will take a small piece of tissue for evaluation (biopsy).

**How is this examination performed?**
Examination under anesthesia is performed in the operating room. You will be asleep with general anesthesia. A scope with attached camera is inserted through your mouth and into your throat, voice box, windpipe, and esophagus.

**How will I feel after the procedure?**
After general anesthesia, you may feel sleepy for a day. You will be able to eat and drink as you did before the procedure. You will receive medication for pain.

You may have the following symptoms:
- A sore throat lasting 1-2 days
- Hoarse voice
- Coughing or spitting up small amount of blood for 1-3 days

**What are the risks of examination under anesthesia?**
A risk is a problem that you might have.

Some risks include
- Reaction to anesthesia
- Bleeding that may recur where the tissue samples were taken
- Damage to teeth
- Swelling where tissue samples were taken may cause difficulty breathing
- Damage to the back of the throat or esophagus (swallowing tube)

**When will I receive my results?**
After the examination under anesthesia, your doctor will be able to tell you what he or she saw and if biopsies were taken. Biopsy results will take at least a few days, sometimes longer. Your doctor will call you or schedule a follow-up visit to review the biopsy results.

**Call your doctor if you experience**
- Severe bleeding or any bleeding >3 days
- Fever >101°F
- Inability to swallow
- Vomiting
- Difficulty breathing

**Action Statement Profile**
- Quality improvement opportunity: Avoid misdiagnosis of malignant lesions with potentially decreased survival. (National Quality Strategy domains: safety, effective treatment)
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High
- Benefits: Avoid misdiagnosis of malignant lesions, avoid inappropriate care (eg, excision, open biopsy), avoid delays in diagnosis, reduce false sense of security
- Risks, harms, costs: Cost of additional diagnostic tests
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Concern by the GDG that some patients receive false reassurance that a cystic mass is not of concern despite studies showing a high rate of malignancy and false-negative biopsies in such masses
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 9. ANCILLARY TESTS:** Clinicians should obtain additional ancillary tests based on the patient’s history and physical examination when a patient with a neck mass is at increased risk for malignancy and/or does not have a diagnosis after FNA and imaging. Recommendation based on nonconsecutive studies, observational studies, case series, and panel consensus with preponderance of benefit over harm.

**Action Statement Profile**
- Quality improvement opportunity: To identify laboratory or other test that can aid in neck mass diagnosis. (National Quality Strategy domains: promoting effective prevention/treatment)
ACTION STATEMENT PROFILE

- Aggregate evidence quality: Grade C, observational studies, case series
- Level of confidence in evidence: Medium
- Benefits: Diagnose neck mass and avoid invasive procedures
- Risks, harms, costs: Direct costs of ancillary tests, false-positive tests, incidental findings, risk of failure to diagnose concurrent malignancy based on these test results
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: The specific tests and timing are at the discretion of the clinician
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 10. EXAMINATION UNDER ANESTHESIA OF THE UPPER AERODIGESTIVE TRACT BEFORE OPEN BIOPSY: Clinicians should recommend examination of the upper aerodigestive tract under anesthesia, before open biopsy, for patients with a neck mass who are at increased risk for malignancy and without a diagnosis or primary site identified, with FNA, imaging, and/or ancillary tests. Recommendation based observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To improve understanding that a neck mass may be a metastatic lesion from a primary aerodigestive site and that identification of these lesions improves treatment outcomes (Tables 8 and 9). (National Quality Strategy domains: safety, effective treatment)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in evidence: High
- Benefits: Potentially identify a primary site of cancer or rule out malignancy, obtain tissue for diagnosis
- Risks, harms, costs: Direct costs of procedures, adverse effects of anesthesia, dental injury, cranial nerve injury, rare complications of endoscopy (bleeding, infection, perforation, airway obstruction)
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception that some clinicians may be performing open biopsy of the neck before, or without, endoscopy during the same trip to the operating room and that endoscopy should preferably be performed prior to open biopsy
- Intentional vagueness: The decision to perform open biopsy is at the discretion of the clinician (after FNA has been performed and is not diagnostic) but is usually performed after the endoscopy if it does not reveal a primary site and a high suspicion for malignancy remains
- Role of patient preferences: Small. May decline intervention.
- Exceptions: Patients who are at increased risk of procedure (anesthesia)
- Policy level: Recommendation
- Differences of opinion: Within the GDG there were differences of opinion about whether the surgeon should be prepared to do a neck dissection at the same time as an open biopsy and frozen section

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