

Clinical Practice Guideline: Hoarseness (Dysphonia) (Update) Executive Summary

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. This guideline provides evidence-based recommendations on treating patients presenting with dysphonia, which is characterized by altered vocal quality, pitch, loudness, or vocal effort that impairs communication and/or quality of life. Dysphonia affects nearly one-third of the population at some point in its life. This guideline applies to all age groups evaluated in a setting where dysphonia would be identified or managed. It is intended for all clinicians who are likely to diagnose and treat patients with dysphonia.

Purpose. The primary purpose of this guideline is to improve the quality of care for patients with dysphonia, based on current best evidence. Expert consensus to fill evidence gaps, when used, is explicitly stated and supported with a detailed evidence profile for transparency. Specific objectives of the guideline are to reduce inappropriate variations in care, produce optimal health outcomes, and minimize harm.

For this guideline update, the American Academy of Otolaryngology—Head and Neck Surgery Foundation selected a panel representing the fields of advanced practice nursing, bronchoesophagology, consumer advocacy, family medicine, geriatric medicine, internal medicine, laryngology, neurology, otolaryngology—head and neck surgery, pediatrics, professional voice, pulmonology, and speech-language pathology.

Action Statements. The guideline update group made *strong recommendations* for the following key action statements (KASs): (1) Clinicians should assess the patient with dysphonia by history and physical examination to identify factors where expedited laryngeal evaluation is indicated. These include but are not limited to recent surgical procedures involving the head, neck, or chest; recent endotracheal intubation; presence of

concomitant neck mass; respiratory distress or stridor; history of tobacco abuse; and whether the patient is a professional voice user. (2) Clinicians should advocate voice therapy for patients with dysphonia from a cause amenable to voice therapy.

The guideline update group made *recommendations* for the following KASs: (1) Clinicians should identify dysphonia in a patient with altered voice quality, pitch, loudness, or vocal effort that impairs communication or reduces quality of life (QOL). (2) Clinicians should assess the patient with dysphonia by history and physical examination for underlying causes of dysphonia and factors that modify management. (3) Clinicians should perform laryngoscopy, or refer to a clinician who can perform laryngoscopy, when dysphonia fails to resolve or improve within 4 weeks or irrespective of duration if a serious underlying cause is suspected. (4) Clinicians should perform diagnostic laryngoscopy, or refer to a clinician who can perform diagnostic laryngoscopy, before prescribing voice therapy and document/communicate the results to the speech-language pathologist (SLP). (5) Clinicians should advocate for surgery as a therapeutic option for patients with dysphonia with conditions amenable to surgical intervention, such as suspected malignancy, symptomatic benign vocal fold lesions that do not respond to conservative management, or glottic insufficiency. (6) Clinicians should offer, or refer to a clinician who can offer, botulinum toxin injections for the treatment of dysphonia caused by spasmodic dysphonia and other types of laryngeal dystonia. (7) Clinicians should inform patients with dysphonia about control/preventive measures. (8) Clinicians should document resolution, improvement or worsened symptoms of dysphonia, or change in QOL of patients with dysphonia after treatment or observation.

The guideline update group made a *strong recommendation against* 1 action: (1) Clinicians should *not* routinely prescribe antibiotics to treat dysphonia. The guideline update group made *recommendations against* other actions: (1) Clinicians

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should *not* obtain computed tomography (CT) or magnetic resonance imaging (MRI) for patients with a primary voice complaint prior to visualization of the larynx. (2) Clinicians should *not* prescribe antireflux medications to treat isolated dysphonia, based on symptoms alone attributed to suspected gastroesophageal reflux disease (GERD) or laryngopharyngeal reflux (LPR), without visualization of the larynx. (3) Clinicians should *not* routinely prescribe corticosteroids in patients with dysphonia prior to visualization of the larynx.

The policy level for the following recommendation about laryngoscopy at any time was an *option*: (1) Clinicians may perform diagnostic laryngoscopy at any time in a patient with dysphonia.

Differences from Prior Guideline

- (1) Incorporating new evidence profiles to include the role of patient preferences, confidence in the evidence, differences of opinion, quality improvement opportunities, and any exclusion to which the action statement does not apply
- (2) Inclusion of 3 new guidelines, 16 new systematic reviews, and 4 new randomized controlled trials
- (3) Inclusion of a consumer advocate on the guideline update group
- (4) Changes to 9 KASs from the original guideline
- (5) New KAS 3 (escalation of care) and KAS 13 (outcomes)
- (6) Addition of an algorithm outlining KASs for patients with dysphonia

Keywords

dysphonia, hoarseness, voice change, voice disturbance, voice disorders, laryngitis, voice, guidelines

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D*ysphonia* (impaired voice production) is a very common complaint, affecting nearly one-third of the population at some point in its life.¹⁻³ The term *dysphonia* is often used interchangeably with *hoarseness*; however, this terminology is imprecise, as hoarseness is a symptom of altered voice quality reported by patients, while dysphonia characterizes impaired voice production as recognized by a clinician.⁴

Dysphonia can affect patients of all ages and sexes but has an increased prevalence among teachers, older adults, and

other persons with significant vocal demands.⁵⁻⁸ In fact, voice problems affect 1 in 13 adults annually.⁹ While patients report a significant impairment of their voices, a relative minority seeks medical care for their voice problems.⁹⁻¹¹ Dysphonia is responsible for frequent health care visits and several billion dollars in lost productivity annually from work absenteeism.¹² Dysphonia is often caused by benign or self-limited conditions but may also be the presenting symptom of a more serious or progressive condition requiring prompt diagnosis and management.

This clinical practice guideline is as an update of, and replacement for, a guideline published in 2009 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).¹³ An update was necessitated by new primary studies and systematic reviews that suggest a need for modifying clinically important recommendations, as well as by the elapsed time since the original guideline. Changes in content and methodology from the prior guideline include

- Incorporating new evidence profiles to include the role of patient preferences, confidence in the evidence, differences of opinion, and quality improvement opportunities
- Inclusion of 3 new guidelines, 16 new systematic reviews, and 4 new randomized controlled trials (RCTs)
- Inclusion of a consumer advocate on the guideline update group (GUG)
- Changes to 9 key action statements (KASs) from the original guideline
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The working definitions found in **Table I** were developed by the guideline panel, and they assume that dysphonia affects people differently. The target population for this guideline includes all individuals presenting with dysphonia, regardless of age. The guideline is intended for all clinicians who diagnose and treat patients with dysphonia, and it applies to any setting in which dysphonia would be identified, monitored, treated, or managed.

There are a number of patients with modifying factors for whom many of the recommendations of the guideline may provide diagnostic and treatment guidance. There is some, though not comprehensive, discussion of these factors and

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Table 1. Dysphonia-Related Definitions.

Dysphonia	Altered vocal quality, pitch, loudness, or vocal effort that impairs communication as assessed by a clinician and affects quality of life
Hoarseness	A symptom of altered voice quality reported by patients
Worsened voice-related quality of life	Self-perceived decrement in function or a decline in economic status as a result of voice-related dysfunction
Dysarthria	A speech disorder due to impaired movement of the structures used for speech production, including the lips, tongue, and complex musculature involved in articulation
Dyspnea	Difficult or labored breathing, shortness of breath
Dysphagia	Disordered or impaired swallowing
Laryngoscopy	Term used to describe visualization of larynx. Unless otherwise specified, its use in this guideline refers to indirect laryngoscopy (visualization of the larynx), which can be done by several methods, including mirror examination, rigid rod-lens telescope examination, rigid rod-lens telescope, flexible fiber optic, or flexible distal chip scopes. Each laryngoscopy technique has specific diagnostic indications.
Stroboscopy	Advanced laryngeal imaging designed to visualize vocal fold vibratory abnormalities that cannot be appreciated using continuous light laryngoscopy. It uses a synchronized flashing light that passes through a laryngoscope.

how they might modify management. A partial list includes patients who have had laryngeal surgery, recent surgical procedures involving the neck or affecting the recurrent laryngeal nerve, recent endotracheal intubation, a history of radiation treatment to the neck, direct laryngeal trauma, craniofacial abnormalities, velopharyngeal insufficiency, and dysarthria (impaired articulation).

Guideline Purpose

The primary purpose of this guideline is to improve the quality of care for patients with dysphonia, based on current best evidence. Expert consensus to fill evidence gaps, when used, is explicitly stated and supported with a detailed evidence profile for transparency. Specific objectives of the guideline are to reduce excessive variation in care, produce optimal health outcomes, and minimize harm.¹⁴⁻¹⁷ Additionally, lack of awareness about dysphonia and its causes are potential barriers to appropriate care. For example, while older adults may experience voice changes as a natural part of aging, some dysphonia in this population may also represent symptoms of a more serious underlying disease. Additionally, a parent may misperceive hoarseness as normal for his or her child. Such assumptions may prevent or delay its evaluation, diagnosis, and treatment of a serious underlying condition. Improved education among all health professionals¹⁸ may allow for improved quality of care and minimization of harm.

The guideline is intended to focus on a limited number of quality improvement opportunities, deemed most important by the working group; it is not intended to be a comprehensive, general guide for managing all patients with dysphonia. It is not intended to be a tool to be utilized by third-party payers to define or deny reimbursement for this condition. In this context, the purpose is to define actions that clinicians can take, regardless of discipline, to deliver quality care. Conversely, the statements in this guideline are not intended to limit or restrict care provided by clinicians based on assessment of individual patients.

This guideline addresses the identification, diagnosis, treatment, and prevention of dysphonia. In addition, it highlights and updates the needs and management options of special populations and patients who have modifying factors. Furthermore, this guideline is intended to enhance the accurate diagnosis of dysphonia and its underlying causes, promote appropriate therapeutic options with outcomes assessment, and improve counseling and education for prevention and management of dysphonia.

Burden of Dysphonia

Prevalence of Dysphonia

Analyses of cross-sectional data from a large nationally representative US medical claims database in 2001 found the point prevalence of dysphonia to be 0.98% (536,943 patients with dysphonia per 55,000,000 patients) in a treatment-seeking population.¹ Consistent with prior studies, rates were higher among females (1.2% vs 0.7% for males) and among those >70 years of age (2.5% vs 0.6%-1.8% for all other age groups).¹⁹⁻²² Of dysphonia-related diagnoses per the *International Classification of Diseases, Ninth Revision*, the most commonly used by physicians were acute laryngitis, nonspecific dysphonia, benign vocal fold lesions (eg, cysts, polyps, nodules), and chronic laryngitis. The true point prevalence of dysphonia-related conditions is likely higher, as most patients with voice changes are not “treatment seeking,” particularly if the dysphonia is transient and related to an upper respiratory infection.¹⁹ An earlier study surveyed randomly selected non-treatment seeking adults in Iowa and Utah and reported a 29.9% cumulative lifetime risk of a voice disorder before 65 years of age.¹⁹

Costs

Costs of treating dysphonia are significant. Direct costs of dysphonia, as estimated from a large administrative database study, were a mean US \$577 to US \$953 per patient per year. If an estimated 5.2 million patients with dysphonia seek treatment

annually, this would translate into total direct health care costs up to US \$13.5 billion.²³ For perspective, these costs are comparable to those spent on conditions such as chronic obstructive pulmonary disease (COPD), asthma, diabetes, and allergic rhinitis.

Quality-of-Life Consequences

Dysphonia primarily affects quality of life (QOL), except when it is a harbinger of a more serious condition (eg, associated with increased risk of mortality or morbidity). QOL consequences of dysphonia are substantial and can be debilitating. Affected patients often suffer social isolation, depression, anxiety, missed work, lost wages, and lifestyle changes.^{11,19,24,25} Studies of voice disorders report QOL implications and work productivity losses comparable to those of patients with asthma, acute coronary syndrome, depression, and COPD.^{11,10} Those with more severe variants (eg, unilateral vocal fold paralysis) have substantially worse QOL and more productivity losses.^{10,26}

Dysphonia as Symptom of Underlying Disease

Dysphonia is a symptom common to a multitude of diseases. It is important to recognize that patients with head and neck cancer may present with dysphonia. In this group, failure to evaluate the larynx can delay cancer diagnosis, resulting in higher staging, need for more aggressive treatment, and reduced survival rates.²⁷ Other conditions that cause dysphonia are neurologic (eg, vocal fold paralysis, spasmodic dysphonia, essential tremor, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis), gastrointestinal (eg, reflux, eosinophilic esophagitis), rheumatologic/autoimmune (eg, rheumatic arthritis, Sjögren's syndrome, sarcoidosis, amyloidosis, granulomatosis with polyangiitis), allergic, pulmonary (eg, COPD), musculoskeletal (eg, muscle tension dysphonia [MTD], fibromyalgia, cervicgia), psychological (functional voice disorders), traumatic (eg, laryngeal fracture, inhalational injury, iatrogenic injury, blunt/penetrating trauma), and infectious (eg, candidiasis), among others. Prevalence of dysphonia within these conditions varies. For example, patients with spasmodic dysphonia or other laryngeal dystonia almost universally manifest with dysphonia. In contrast, not all patients with reflux have dysphonia.

Muscle Tension Dysphonia

Current *International Classification of Diseases, Ninth Revision* or *Tenth Revision* codes are imprecise for voice disorders. It is likely that a large proportion of patients with nonspecific dysphonia and chronic laryngitis that were identified in the aforementioned large administrative database studies ultimately were diagnosed with MTD. This condition is a voice disorder that constitutes 10% to 40% of caseloads in voice centers,²⁸ and it is characterized by increased laryngeal musculoskeletal tension with excessive recruitment in the larynx and pharynx with concomitant disruption of efficient vibratory parameters.²⁹ MTD is further classified as primary or secondary. *Primary* occurs in the absence of identifiable fixed laryngeal disorders, while *secondary* refers to MTD that

occurs in conjunction with laryngeal disorders.³⁰ Both types present with variable symptomatology, including voice change, vocal fatigue, effortful voice production, change in habitual pitch, reduced vocal range, pain with voice use, muscular cramping, and neck stiffness.

Dysphonia and Age

Voice disorders affect all ages, but some evidence suggests that risks are higher in pediatric and elderly (>65 years of age) populations. An estimated 23.4% of children have dysphonia at some point,³¹⁻³⁴ with increased prevalence among boys and those in the 8- to 14-year age range.³⁵

Prevalence is also substantially higher among older adults with presbylarynx (ie, age-related laryngeal changes).^{8,20,36-43} In a large nationally representative administrative insurance claims database,^{1,22} the prevalence rate of dysphonia in the treatment-seeking elderly population was 1.3% among those 60 to 69 years old and 2.5% among patients >70 old.¹ The most common diagnoses coded in this cohort were acute and chronic laryngitis, nonspecific dysphonia, and laryngeal lesions. An earlier study that surveyed non-treatment seeking elderly volunteers reported that 47% had had a voice disorder during their lifetimes and 29% were actively experiencing dysphonia.⁴⁴ Another study surveyed 120 elderly occupants of an independent living facility in Atlanta and found a 20-percentage point prevalence of voice disturbance based on voice-related QOL scores.⁴⁵

Dysphonia and Occupation

People in vocations with high vocal demands have increased likelihood of developing dysphonia. This includes but is not limited to singers and entertainers,^{46,47} legal professionals,⁴⁸ teachers,^{49,50} telemarketers,^{5,51,52} aerobics instructors,⁶ clergy,⁴⁸ and coaches.⁵³

Dysphonia can affect a person's ability to work.⁵⁴ An estimated 28 million workers in the United States experience voice problems daily.⁴⁸ In the general population, 7.2% of individuals surveyed missed work for ≥ 1 days within the preceding year because of a voice problem,¹⁹ and 1 out of 10 individuals with voice disorders file short-term disability claims.⁵⁵ In fact, 20% of teachers miss work due to dysphonia,²¹ and absenteeism in this occupation alone has associated economic ramifications of \$2.5 billion in the United States annually.⁴⁸

Iatrogenic Dysphonia

Vocal fold injury after intubation is common, with estimates ranging widely from 2.3% to 84% depending on the age range assessed (infants vs adults), injury definition, and ascertainment methodology.⁵⁶⁻⁵⁹ Estimated rates of dysphonia resulting from injury to the recurrent laryngeal nerve after thyroidectomy and anterior cervical spine surgery also range widely in the literature: 0.85% to 8.5%⁶⁰⁻⁶⁹ and 1.69% to 24.2%,⁷⁰⁻⁷³ respectively. Cardiothoracic procedures in children and adults represent another source of recurrent laryngeal nerve injury.⁷⁴⁻⁷⁷ It is important to emphasize that the wide ranges listed are attributed to different assessment criteria, study

designs/ascertainment methodology, and patient populations considered and further highlight the overall lack of understanding of the population-level burden of iatrogenic voice-related disease.

Medication Side Effects

Medication side effects are another etiology of and contributor to dysphonia. While many medications have dysphonia as a potential side effect, inhaled steroids and drying agents (eg, anticholinergics,^{78,79} antihistamines,⁸⁰ decongestants,⁸⁰ and antihypertensives⁸¹) are most closely linked to dysphonia. Steroid inhalers may cause fungal and nonspecific laryngitis.⁸²⁻⁸⁵ Drying medications were associated with 2.32- and 4.52-fold increased odds of dysphonia in a recent cross-sectional study.⁷⁸

CPG Outcome Measures

The primary outcome considered in this guideline is measured change in QOL. Secondary outcomes include assessment of harms (eg, complications and adverse events). Economic consequences, adherence to therapy, absenteeism, communication function, and voice-related health care utilization were also considered. The high prevalence, significant individual and societal implications, diversity of interventions, and lack of consensus make this an important condition for an up-to-date, evidence-based practice guideline.

Methods

General Methods

In developing this update of the evidence-based clinical practice guideline, the methods outlined in the AAO-HNSF's "Clinical Practice Guideline Development Manual, Third Edition" were followed explicitly.⁸⁶

A draft of the original hoarseness guideline¹³ was sent to a panel of expert reviewers from the fields of advanced practice nursing, bronchoesophagology, consumer advocacy, family medicine, geriatric medicine, internal medicine, laryngology, neurology, otolaryngology–head and neck surgery, pediatrics, professional voice, pharmacy, and speech-language pathology. Several group members had significant prior experience in developing clinical practice guidelines. The reviewers concluded that the original guideline action statements remained valid but should be updated with minor modifications. Suggestions were also made for new KASs.

Literature Search

An information specialist conducted 3 literature searches from December 2015 through April 2016 using a validated filter strategy to identify clinical practice guidelines (CPGs), systematic reviews (SRs), and RCTs. The search terms used were as follows: ("hoarseness"[MeSH Terms] OR "hoarseness"[tw] OR "hoarse"[tw] OR "aphonia"[MeSH Terms] OR "aphonia"[tw] OR "phonation disorder"[tw] OR "dysphonia"[MeSH Terms] OR "dysphonia"[tw] OR "phonation disorders"[tw] OR "voice disorder"[tw] OR "voice disorders"[tw] OR "vocal disorder"[tw] OR "vocal disorders"[tw] OR laryngitis[tw] OR "laryngeal disorder"[tw] OR "laryngeal disorders"[tw]). These search terms

were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The English-language searches were performed in multiple databases, including HSTAT, AHRQ, BIOSIS Previews, CAB Abstracts, AMED, EMBASE, GIN International Guideline Library, Cochrane Library (Cochrane Database of Systematic Reviews, DARE, HTA Database, NHS EED), Australian National Health and Medical Research Council, New Zealand Guidelines Group, SIGN, TRIP Database, CMA Infobase, National Guideline Clearinghouse, PubMed Search, and CINAHL.

The initial English-language search identified 106 clinical practice guidelines, 561 systematic reviews, and 516 RCTs published in 2008 or later. Clinical practice guidelines were included if they met quality criteria of (1) an explicit scope and purpose, (2) multidisciplinary stakeholder involvement, (3) systematic literature review, (4) explicit system for ranking evidence, and (5) explicit system for linking evidence to recommendations. Systematic reviews were emphasized and included if they met quality criteria of (1) a clear objective and methodology, (2) an explicit search strategy, and (3) valid data extraction methods. RCTs were included if they met the following quality criteria: (1) trials involved study randomization; (2) trials were described as double-blind; and (3) trials denoted a clear description of withdrawals and dropouts of study participants. After removal of duplicates, irrelevant references, and non-English language articles, 6 clinical practice guidelines, 55 systematic reviews, and 24 RCTs were retained. In certain instances, targeted searches were performed by GUG members to address gaps from the systematic searches identified in writing the guideline from June 2016 through February 2017. Therefore, in total, the evidence supporting this guideline includes 3 clinical practice guidelines, 16 systematic reviews, and 4 RCTs. 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 RCTs and observational studies, as needed, to supplement the systematic reviews or to fill gaps when a review was not available.

The AAO-HNSF assembled a GUG representing the disciplines of advanced practice nursing, bronchoesophagology, consumer advocacy, family medicine, geriatric medicine, internal medicine, laryngology, neurology, otolaryngology–head and neck surgery, pediatrics, professional voice, pulmonology, and speech-language pathology. The GUG had several conference calls and 1 in-person meeting, during which it defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each KAS, identified other quality improvement opportunities, reviewed the literature search results, and drafted the document.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with our current development standards.⁸⁶ Information was added to the action statement profiles regarding quality improvement opportunities, level of

confidence in the evidence, differences of opinion, role of patient preferences, and any exclusion to which the action statement does not apply. New KASs were 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. Electronic decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) was used to facilitate creating actionable recommendations and evidence profiles.⁸⁷

The updated guideline underwent GuideLine Implementability Appraisal (GLIA) to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.⁸⁸ The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal. The final draft of the updated clinical practice guideline was revised on the basis of comments received during multidisciplinary peer review, open public comment, and journal editorial peer review. 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 produce optimal health outcomes for patients, to minimize harm, and to reduce inappropriate variations in clinical care. The evidence-based approach to guideline development requires that 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 are anticipated when the statement is followed. The definitions for evidence-based statements are listed in **Tables 2**^{89,90} and **Table 3**.⁹¹

Guidelines are not intended to supersede professional judgment but rather may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a “strong recommendation” as compared with a “recommendation.” “Options” offer the most opportunity for practice variability.⁹¹ Clinicians should always act and decide in a way that they believe will best serve their patients’ interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.⁹¹ Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel 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 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,⁹² 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.⁹³

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: an evidence-based KAS in bold, followed by the strength of the recommendation in italics. Each KAS is followed by the “action statement profile,” which lists quality improvement opportunities, aggregate evidence quality, level of confidence in the evidence, the risks and costs of carrying out the prescribed action as determined by the panel, and a benefit-harm assessment. Additionally, there is an explicit statement of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exclusions 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 4**.

For the purposes of this guideline, *shared decision making* refers to the exchange of information regarding treatment risks and benefits, as well as the expression of patient preferences and values, which result in mutual responsibility in decisions regarding treatment and care.⁹⁴ In cases where evidence is weak or benefits are unclear, the practice of shared decision making is extremely useful, wherein the management decision is made by a collaborative effort between the clinician and an informed patient. Factors related to patient preference include, but are not limited to, absolute benefits (numbers needed to treat), adverse effects (number needed to harm), cost of medications or procedures, and frequency and duration of treatment.

STATEMENT 1. IDENTIFICATION OF ABNORMAL VOICE: Clinicians should identify dysphonia in a patient with altered voice quality, pitch, loudness, or vocal effort that impairs communication or reduces QOL. *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile: I

- **Quality improvement opportunity:** To promote awareness of dysphonia by all clinicians as a condition that may require intervention or additional investigation. National Quality Strategy domain: Prevention and Treatment of Leading Causes of Morbidity and Mortality.

Table 2. Aggregate Grades of Evidence by Question Type.^a

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review ^b of randomized trials	Systematic review ^b of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review ^b of cross-sectional studies with consistently applied reference standard and blinding	Systematic review ^b of inception cohort studies ^c
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies ^c
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	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	Nonconsecutive studies; case-control studies; or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series or case-control studies, or poor quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

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

^aAdapted from Howick and coworkers.⁹⁰

^bA systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

^cA 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.

- **Aggregate evidence quality:** Grade C, observational studies for symptoms, with 1 systematic review of QOL in voice disorders and 2 systematic reviews on medication side effects
- **Level of confidence in evidence:** High
- **Benefit:** Timely recognition of the need to search for an underlying etiology; identify patients who may benefit from treatment; discourage the perception of dysphonia as a trivial condition that does not warrant attention
- **Risks, harms, costs:** Potential anxiety related to diagnosis; time expended in diagnosis, documentation, and discussion
- **Benefits-harm assessment:** Preponderance of benefits over harm
- **Value judgments:** The group believes that this is a critical component to caring for patients with altered voice, but it was constrained from calling this a strong recommendation from a lack of A- or B-level evidence
- **Intentional vagueness:** None
- **Role of patient preferences:** Small
- **Exclusions:** None
- **Policy level:** Recommendation
- **Differences of opinions:** None

STATEMENT 2. IDENTIFYING UNDERLYING CAUSE OF DYSPHONIA: Clinicians should assess the patient with dysphonia by history and physical examination for underlying causes of dysphonia and factors that modify management. *Recommendation* based on observational studies with a preponderance of benefit over harm.

Action Statement Profile: 2

- **Quality improvement opportunity:** To guide the expediency and nature of recommended treatments/investigations through identification of potential underlying causes of the dysphonia. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination.
- **Aggregate evidence quality:** Grade C, observational studies
- **Level of confidence in evidence:** High
- **Benefit:** To identify potential causative factors of the dysphonia, increase awareness of underlying causes of dysphonia, identify patients at risk for serious underlying conditions, identify underlying cause allows for targeted treatment
- **Risks, harms, costs:** None

Table 3. Guideline Definitions for Evidence-Based Statements.

Statement	Definition	Implication
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). ^a In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation) but that the quality of evidence is not as strong (grade B or C). ^a In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) ^a or that well-done studies (grade A, B, or C) ^a show little clear advantage to one approach versus another.	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.

^aAmerican Academy of Pediatrics classification scheme.⁹¹

- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Further management of dysphonia is completely dependent on the underlying cause. The group thought that while this seems obvious, it was an opportunity to educate clinicians about potential etiologies
- **Intentional vagueness:** None
- **Role of patient preferences:** Small
- **Exclusions:** None
- **Policy level:** Strong recommendation
- **Differences of opinions:** None

STATEMENT 3. ESCALATION OF CARE: Clinicians should assess the patient with dysphonia by history and physical examination to identify factors where expedited laryngeal evaluation is indicated. These include but are not limited to recent surgical procedures involving the head, neck, or chest; recent endotracheal intubation; presence of concomitant neck mass; respiratory distress or stridor; history of tobacco abuse; and whether the patient is a professional voice user. *Strong recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile: 3

- **Quality improvement opportunity:** To encourage early referral of dysphonic patients whose history, symptoms, or physical examination is concerning for a serious underlying etiology. National Quality Strategy domains: Prevention and Treatment of Leading Causes

of Morbidity and Mortality; Effective Communication and Care Coordination; Patient Safety.

- **Aggregate evidence quality:** Grade B, based on overwhelmingly consistent evidence from observational studies
- **Level of confidence in evidence:** High
- **Benefit:** To identify factors early in the course of management that could influence the timing of diagnostic procedures, choice of interventions, or provision of follow-up care; identify risk factors; identify populations for whom early or more aggressive intervention may be warranted (ie, professional voice)
- **Risks, harms, costs:** Time in assessment
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Importance of history taking and identifying modifying factors as an essential component of providing quality care
- **Intentional vagueness:** The term *expedited* does not specify exact timing
- **Role of patient preferences:** Moderate (small: in the setting of a neck mass with dysphonia or concern for malignancy)
- **Exclusions:** None
- **Policy level:** Strong recommendation
- **Differences of opinions:** None

STATEMENT 4A. LARYNGOSCOPY AND DYSPHONIA: Clinicians may perform diagnostic laryngoscopy at any time in a patient with dysphonia. *Option based on observational studies, expert opinion, and a balance of benefit and harm.*

Table 4. Summary of Evidence-Based Statements.

Statement	Action	Strength
1. Identification of abnormal voice	Clinicians should identify dysphonia in a patient with altered voice quality, pitch, loudness, or vocal effort that impairs communication or reduces QOL.	Recommendation
2. Identifying underlying cause of dysphonia	Clinicians should assess the patient with dysphonia by history and physical examination for underlying causes of dysphonia and factors that modify management.	Recommendation
3. Escalation of care	Clinicians should assess the patient with dysphonia by history and physical examination to identify factors where expedited laryngeal evaluation is indicated. These include but are not limited to recent surgical procedures involving the head, neck, or chest; recent endotracheal intubation; presence of concomitant neck mass; respiratory distress or stridor; history of tobacco abuse; and whether the patient is a professional voice user.	Strong recommendation
4a. Laryngoscopy and dysphonia	Clinicians may perform diagnostic laryngoscopy at any time in a patient with dysphonia.	Option
4b. Need for laryngoscopy in persistent dysphonia	Clinicians should perform laryngoscopy, or refer to a clinician who can perform laryngoscopy, when dysphonia fails to resolve or improve within 4 weeks or irrespective of duration if a serious underlying cause is suspected.	Recommendation
5. Imaging	Clinicians should <i>not</i> obtain computed tomography (CT) or magnetic resonance imaging (MRI) for patients with a primary voice complaint prior to visualization of the larynx.	Recommendation against
6. Antireflux medication and dysphonia	Clinicians should <i>not</i> prescribe antireflux medications to treat isolated dysphonia, based on symptoms alone attributed to suspected gastroesophageal reflux disease (GERD) or laryngopharyngeal reflux (LPR), without visualization of the larynx.	Recommendation against
7. Corticosteroid therapy	Clinicians should <i>not</i> routinely prescribe corticosteroids for patients with dysphonia prior to visualization of the larynx.	Recommendation against
8. Antimicrobial therapy	Clinicians should <i>not</i> routinely prescribe antibiotics to treat dysphonia.	Strong recommendation against
9a. Laryngoscopy prior to voice therapy	Clinicians should perform diagnostic laryngoscopy, or refer to a clinician who can perform diagnostic laryngoscopy, before prescribing voice therapy and document/communicate the results to the speech-language pathologist (SLP).	Recommendation
9b. Advocating for voice therapy	Clinicians should advocate voice therapy for patients with dysphonia from a cause amenable to voice therapy.	Strong recommendation
10. Surgery	Clinicians should advocate for surgery as a therapeutic option for patients with dysphonia with conditions amenable to surgical intervention, such as suspected malignancy, symptomatic benign vocal fold lesions that do not respond to conservative management, or glottic insufficiency.	Recommendation
11. Botulinum toxin	Clinicians should offer, or refer to a clinician who can offer, botulinum toxin injections for the treatment of dysphonia caused by spasmodic dysphonia and other types of laryngeal dystonia.	Recommendation
12. Education/prevention	Clinicians should inform patients with dysphonia about control/preventive measures.	Recommendation
13. Outcomes	Clinicians should document resolution, improvement, or worsened symptoms of dysphonia or change in QOL among patients with dysphonia after treatment or observation.	Recommendation

Action Statement Profile: 4A

- Quality improvement opportunity: To highlight the important role of visualizing the larynx and vocal folds in treating a patient with dysphonia. National Quality Strategy domains: Prevention and Treatment of

Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination; Patient Safety.

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High

- **Benefit:** establishing the underlying diagnosis, possible reduction in cost, improved diagnostic accuracy, appropriate referrals, appropriate treatment, avoid missed or delayed diagnosis, reduced anxiety by establishing diagnosis
- **Risks, harms, costs:** Patient discomfort, cost of examination, procedure related morbidity
- **Benefits-harm assessment:** Balance of benefit and harm
- **Value judgments:** Laryngoscopy is an essential tool for diagnosing the cause of dysphonia and should be available to those who can perform it; however, dysphonia is often self-limited and may resolve spontaneously without a diagnosis
- **Intentional vagueness:** None
- **Role of patient preferences:** Moderate
- **Exclusions:** None
- **Policy level:** Option
- **Differences of opinions:** None

STATEMENT 4B. NEED FOR LARYNGOSCOPY IN PERSISTENT DYSPHONIA: Clinicians should perform laryngoscopy, or refer to a clinician who can perform laryngoscopy, when dysphonia fails to resolve or improve within 4 weeks or irrespective of duration if a serious underlying cause is suspected. *Recommendation based on observational studies, expert opinion, and a preponderance of benefit over harm.*

Action Statement Profile: 4B

- **Quality improvement opportunity:** To highlight the important role of visualizing the larynx and vocal folds in treating a patient with dysphonia, especially if the dysphonia fails to improve within 4 weeks' onset. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination.
- **Aggregate evidence quality:** Grade C, observational studies on the natural history of benign laryngeal disorders; grade C for observational studies plus expert opinion on defining what constitutes a serious underlying condition
- **Level of confidence in evidence:** High
- **Benefit:** Avoid missed or delayed diagnosis of serious conditions in patients without additional signs and/or symptoms to suggest underlying disease; permit prompt assessment of the larynx when serious concern exists
- **Risks, harms, costs:** Potential for delay in diagnosis; procedure-related morbidity; procedure related expense; patient discomfort
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** A need exists to balance timely diagnostic intervention with the potential for overutilization and excessive cost. The guideline update

panel debated the optimal time for assessment of the larynx using a consensus-based approach and agreed on 4 weeks with the option to proceed more promptly based on clinical circumstances

- **Intentional vagueness:** The term *serious underlying concern* is subject to the discretion of the clinician. Some conditions are clearly serious, but for other patients, the seriousness of the condition is dependent on the patient. Intentional vagueness was incorporated to allow for clinical judgment in the expediency of evaluation
- **Role of patient preferences:** If there is a serious underlying concern, then there is a limited role for patient preference; however, for patients without a serious underlying concern, the role for patient preference is moderate
- **Exclusions:** None
- **Policy level:** Recommendation
- **Differences of opinions:** There was some disagreement about whether the time frame should be 4 or 6 weeks. After casting their votes, 10 panel members favored a 4-week time frame, and 5 panel members favored a 6-week time frame.

STATEMENT 5. IMAGING: Clinicians should not obtain computed tomography (CT) or magnetic resonance imaging (MRI) for patients with a primary voice complaint prior to visualization of the larynx. *Recommendation against imaging based on observational studies of harm, absence of evidence concerning benefit, and a preponderance of harm over benefit.*

Action Statement Profile: 5

- **Quality improvement opportunity:** To reduce variations of care and unnecessary expense as well as harm from radiation and/or contrast exposure. National Quality Strategy domain: Making Quality Care More Affordable.
- **Aggregate evidence quality:** Grade C, observational studies regarding the adverse events of CT and MRI; no evidence identified concerning benefits in patients with dysphonia before laryngoscopy
- **Level of confidence in evidence:** High
- **Benefit:** Avoid unnecessary testing; avoid overdiagnosis; minimize cost and adverse events; maximizing the diagnostic yield of CT and MRI when indicated; avoid radiation
- **Risks, harms, costs:** Potential for delayed/missed diagnosis
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** None
- **Intentional vagueness:** None
- **Role of patient preferences:** Small
- **Exclusions:** None
- **Policy level:** Recommendation against
- **Differences of opinions:** None

STATEMENT 6. ANTIREFLUX MEDICATION AND DYSPHONIA: Clinicians should not prescribe antireflux medications to treat isolated dysphonia, based on symptoms alone attributed to suspected gastroesophageal reflux disease (GERD) or laryngopharyngeal reflux (LPR), without visualization of the larynx. *Recommendation against prescribing based on randomized trials with limitations and observational studies with a preponderance of harm over benefit.*

Action Statement Profile: 6

- **Quality improvement opportunity:** To limit widespread use of antireflux medications as empiric therapy for dysphonia without symptoms of GERD or seeing changes in the larynx associated with LPR or laryngitis, given limited evidence of benefit and the potential adverse effects of the medications. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
- **Aggregate evidence quality:** Grade B, randomized trials with limitations showing lack of benefits for antireflux therapy for patients with laryngeal symptoms alone, including dysphonia; observational studies with inconsistent or inconclusive results; inconclusive evidence regarding the prevalence of dysphonia as the only manifestation of reflux disease
- **Level of confidence in evidence:** Medium, based on small inconsistent randomized trials with heterogeneous entry criteria and poorly defined outcome measures
- **Benefit:** Avoidance of unnecessary therapy; reduced cost; avoidance of complications from proton pump inhibitors; avoidance of diagnostic and treatment delay due to course of proton pump inhibitor therapy
- **Risks, harms, costs:** Potential withholding of therapy from patients who may benefit
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** The committee thought that there is general overuse of these medications and that they have limited usefulness for most patients with dysphonia but that there may be a role for antireflux medications in a subset of hard-to-define patients. We also recognize that there is a role for these medications to treat gastroesophageal reflux
- **Intentional vagueness:** None
- **Role of patient preferences:** Small
- **Exclusions:** None
- **Policy level:** Recommendation against
- **Differences of opinions:** The panel was divided about whether to include the terms *GERD* and *LPR* in the action statement or to leave it simply as symptoms alone. The majority favored inclusion of these terms in the KAS

STATEMENT 7. CORTICOSTEROID THERAPY: Clinicians should not routinely prescribe corticosteroids for

patients with dysphonia prior to visualization of the larynx. *Recommendation against prescribing based on randomized trials showing adverse events and absence of clinical trials demonstrating benefits with a preponderance of harm over benefit for steroid use.*

Action Statement Profile 7

- **Quality improvement opportunity:** To discourage the empiric use of steroids for dysphonia prior to laryngeal examination. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
- **Aggregate evidence quality:** Grade B, randomized trials showing increased incidence of adverse events associated with orally administered steroids; absence of clinical trials demonstrating any benefit of steroid treatment on outcomes
- **Level of confidence in evidence:** High
- **Benefit:** Avoid potential adverse events associated with unproven therapy
- **Risks, harms, costs:** None
- **Benefits-harm assessment:** Preponderance of harm over benefit for steroid use
- **Value judgments:** Avoid adverse events of ineffective or unproven therapy
- **Intentional vagueness:** The word *routine* is used to acknowledge that there may be specific situations, based on laryngoscopy results, or other associated conditions that may justify steroid use on an individualized basis
- **Role of patient preferences:** Small; there is a role for shared decision making in weighing the harms of steroids against the potential yet unproven benefit in specific circumstances (ie, professional or avocation voice use and acute laryngitis)
- **Exclusions:** Children with croup
- **Policy level:** Recommendation against
- **Differences of opinions:** None

STATEMENT 8. ANTIMICROBIAL THERAPY: Clinicians should not routinely prescribe antibiotics to treat dysphonia. *Strong recommendation against prescribing based on systematic reviews and randomized trials showing ineffectiveness of antibiotic therapy and a preponderance of harm over benefit.*

Action Statement Profile: 8

- **Quality improvement opportunity:** To discourage the misuse of antibiotics. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
- **Aggregate evidence quality:** Grade A, systematic reviews showing no benefit for antibiotics for acute laryngitis or upper respiratory tract infection; grade A evidence showing potential harms of antibiotic therapy

- Level of confidence in evidence: High
- Benefit: Avoidance of ineffective therapy, unnecessary cost, and antibiotic resistance
- Risks, harms, costs: Potential for failing to treat bacterial, fungal, or mycobacterial causes of dysphonia
- Benefits-harm assessment: Preponderance of harm over benefit if antibiotics are prescribed
- Value judgments: Importance of limiting antimicrobial therapy to treating bacterial or fungal infections
- Intentional vagueness: The word *routine* is used in the KAS to discourage empiric therapy yet to acknowledge that there are occasional circumstances where antimicrobial use may be appropriate
- Role of patient preferences: None
- Exclusions: Patients with dysphonia caused by bacterial, fungal, or mycobacterial infection
- Policy level: Strong recommendation against
- Differences of opinions: None

STATEMENT 9A. LARYNGOSCOPY PRIOR TO VOICE THERAPY: Clinicians should perform diagnostic laryngoscopy, or refer to a clinician who can perform diagnostic laryngoscopy, before prescribing voice therapy and document/communicate the results to the speech-language pathologist (SLP). *Recommendation based on observational studies showing benefit and a preponderance of benefit over harm.*

Action Statement Profile: 9A

- Quality improvement opportunity: To encourage the routine use of diagnostic laryngoscopy for patients with dysphonia (hoarseness) before initiation of voice therapy and to promote the most effective treatment practices for patients with dysphonia. National Quality Strategy domains: Effective Communication and Care Coordination; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
- Aggregate evidence quality: Grade C, observational studies of the benefit of laryngoscopy for voice therapy
- Level of confidence in evidence: High
- Benefit: Avoid delay in diagnosing laryngeal conditions not treatable with voice therapy; optimize voice therapy by allowing targeted therapy
- Risks, harms, costs: Delay in initiation of voice therapy; cost of the laryngoscopy and associated clinician visit; patient discomfort
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: To ensure no delay in identifying pathology not treatable with voice therapy. The SLP should not initiate therapy prior to laryngoscopy
- Intentional vagueness: None
- Role of patient preferences: Small
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

STATEMENT 9B. ADVOCATING FOR VOICE THERAPY: Clinicians should advocate voice therapy for patients with dysphonia from a cause amenable to voice therapy. *Strong recommendation based on systematic reviews and randomized trials with a preponderance of benefit over harm.*

Action Statement Profile: 9B

- Quality improvement opportunity: To promote effective communication with patients and to promote the most effective prevention and treatment practices for patients with dysphonia. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality; Making Quality Care More Affordable.
- Aggregate evidence quality: Grade A, RCTs and systematic reviews
- Level of confidence in evidence: High
- Benefit: Improve voice-related QOL; prevent relapse; potentially prevent need for more invasive therapy
- Risks, harms, costs: No harm reported in controlled trials; cost of treatment
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Voice therapy is underutilized in managing dysphonia despite efficacy; advocacy is needed
- Intentional vagueness: Deciding which patients will benefit from voice therapy is often determined by the voice therapist (SLP)
- Role of patient preferences: Small
- Exclusions: Patients unable to participate in therapy
- Policy level: Strong recommendation
- Differences of opinions: None

STATEMENT 10. SURGERY: Clinicians should advocate for surgery as a therapeutic option for patients with dysphonia with conditions amenable to surgical intervention, such as suspected malignancy, symptomatic benign vocal fold lesions that do not respond to conservative management, or glottic insufficiency. *Recommendation based on observational studies demonstrating a benefit of surgery in these conditions and a preponderance of benefit over harm.*

Action Statement Profile: 10

- Quality improvement opportunity: To advocate that clinicians discuss and consider surgery as a therapeutic option for dysphonic patients whose underlying etiology is amenable to surgical intervention. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
- Aggregate evidence quality: Grade B, in support of surgery to reduce dysphonia and improve voice quality in selected patients based on observational studies overwhelmingly demonstrating the benefit of surgery
- Level of confidence in evidence: High

- **Benefit:** Potential for improved voice outcomes in carefully selected patients
- **Risks, harms, costs:** None
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Surgical options for treating dysphonia are not always recognized
- **Intentional vagueness:** None
- **Role of patient preferences:** Small
- **Exclusions:** None
- **Policy level:** Recommendation
- **Differences of opinions:** None

STATEMENT 11. BOTULINUM TOXIN: Clinicians should offer, or refer to a clinician who can offer, botulinum toxin injections for the treatment of dysphonia caused by spasmodic dysphonia and other types of laryngeal dystonia. *Recommendation based on RCTs with minor limitations and preponderance of benefit over harm.*

Action Statement Profile: 11

- **Quality improvement opportunity:** To expedite referral for suspected spasmodic dysphonia. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
- **Aggregate evidence quality:** Grade B, few controlled trials, diagnostic studies with minor limitations, and overwhelmingly consistent evidence from observational studies
- **Level of confidence in evidence:** High
- **Benefit:** Improved voice quality and voice-related QOL
- **Risks, harms, costs:** Dysphagia, airway obstruction, breathy voice, direct costs of treatment, time off work, and indirect costs of repeated treatments
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** Botulinum toxin is beneficial despite the potential need for repeated treatments given the limited availability of other effective interventions for spasmodic dysphonia
- **Intentional vagueness:** None
- **Role of patient preferences:** Large
- **Exclusions:** Allergy to botulinum toxin
- **Policy level:** Recommendation
- **Differences of opinions:** None

STATEMENT 12. EDUCATION/PREVENTION: Clinicians should inform patients with dysphonia about control/preventive measures. *Recommendation based on observational studies, small-sample RCTs, expert opinion, and a preponderance of benefit over harm.*

Action Statement Profile: 12

- **Quality improvement opportunity:** To provide guidance to clinicians in educating patients on behavioral

strategies and environmental measures that may prevent or decrease the risk of dysphonia. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.

- **Aggregate evidence quality:** Grade C, evidence based on observational studies, small-sample RCTs, expert opinion, and a preponderance of benefit over harm
- **Level of confidence in evidence:** High
- **Benefit:** Possible decreased risk of recurrence of dysphonia; improved vocal hygiene may reduce dysphonia; possible prevention of dysphonia in persons at high risk
- **Risks, harms, costs:** Time of education; cost of potentially ineffective interventions
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** None
- **Intentional vagueness:** None
- **Role of patient preferences:** Small role in terms of receiving information from clinician; moderate to large role in shared decision making that involves choosing specific preventive and control measures to use
- **Exclusions:** None
- **Policy level:** Recommendation
- **Differences of opinions:** None

STATEMENT 13. OUTCOMES: Clinicians should document resolution, improvement, or worsened symptoms of dysphonia or change in QOL among patients with dysphonia after treatment or observation. *Recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm.*

Action Statement Profile: 13

- **Quality improvement opportunity:** To ensure that patients with dysphonia are followed until the dysphonia has improved or resolved or the underlying condition has been diagnosed and appropriately managed. National Quality Strategy domain: Effective Communication and Care Coordination.
- **Aggregate evidence quality:** Grade C, recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm
- **Level of confidence in evidence:** High
- **Benefit:** Document the final status of dysphonia, communicate with referring clinicians, document favorable outcomes or failures of treatment
- **Risks, harms, costs:** Cost of follow-up visits
- **Benefits-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** None
- **Intentional vagueness:** The time frame for assessing outcome is not stated
- **Role of patient preferences:** Small

- **Exclusions:** None
- **Policy level:** Recommendation
- **Differences of opinions:** None

Disclaimer

This clinical practice guideline is not intended as an exhaustive source of guidance for managing dysphonia (hoarseness). 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 provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates. These do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF 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.

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Appendix: Frequently Asked Questions about Voice Therapy

Why Is Voice Therapy Recommended for Dysphonia?

Voice therapy has been demonstrated to be effective for dysphonia across the life span from children to older adults.^{A1,A2} Voice therapy is the first line of treatment for vocal fold lesions such as vocal nodules, polyps, or cysts.^{A3,A4} These lesions often occur in people with vocally intense occupations, including teachers, attorneys, or clergy.^{A5} Another possible cause of these lesions is the vocal overdoing commonly seen in sports enthusiasts; in socially active, aggressive, or loud children; or in high-energy adults who often speak loudly.^{A6-A9} Voice therapy, specifically the Lee Silverman voice therapy method, has been demonstrated to be the most effective method of treating the lower-volume, lower-energy, and rapid-rate voice/speech of individuals with Parkinson's disease.^{A10,A11}

Voice therapy has been used to treat dysphonia concurrently with other medical therapies, such as botulinum toxin injections for spasmodic dysphonia and/or tremor.^{A12,A13} Voice therapy has been used alone in the treatment of unilateral vocal fold paralysis,^{A14,A15} presbyphonia,^{A16} and vocal process granuloma,^{A17} and it has been used to improve the outcome of surgical procedures, as in vocal fold augmentation^{A18} or thyroplasty.^{A19} Voice therapy is an important component of any comprehensive surgical treatment for dysphonia.^{A20}

What Happens in Voice Therapy?

Voice therapy is a program designed to reduce dysphonia through guided change in vocal behaviors and lifestyle changes. Voice therapy consists of a variety of tasks designed to eliminate harmful vocal behavior, shape healthy vocal behavior, and assist in vocal fold wound healing after surgery or injury. Voice therapy for dysphonia generally consists of 1 or 2 therapy sessions each week for 4 to 8 weeks.^{A21} The duration of therapy is determined by the origin of the dysphonia and severity of the problem, co-occurring medical therapy, and, importantly, patient commitment to the practice and generalization of new vocal behaviors outside the therapy session.^{A22}

Who Provides Voice Therapy?

Certified and licensed SLPs are health care professionals with the expertise needed to provide effective behavioral treatment for dysphonia.^{A23}

How Do I Find a Qualified SLP Who Has Experience in Voice?

The American Speech-Language-Hearing Association (ASHA) is an excellent resource for finding a certified SLP by going to the ASHA website (www.asha.org) or by accessing ASHA's online search engine, called ProFind at <http://www.asha.org/profind/>. You may also contact ASHA's Action Center, Monday through Friday (8:30 AM–5:00 pm) at 800-498-

2071; fax, 301-296-8580; TTY (text telephone communication device), 301-296-5650; email, actioncenter@asha.org.

Does Insurance Cover Voice Therapy?

Generally, Medicare, under the guidelines for coverage of speech therapy, will cover voice therapy if provided by a certified and licensed SLP, if ordered by a physician, and if deemed medically necessary for the diagnosis. Medicaid varies from state to state but generally covers voice therapy, under the rules for speech therapy, up to the age of 18 years. It is best to contact your local Medicaid office, as there are state differences and program differences. Private insurance companies vary, and the consumer is guided to contact her or his insurance company for specific guidelines for the purchased policies.

Are Speech Therapy and Voice Therapy the Same?

Speech therapy is a term that encompasses a variety of therapies, including voice therapy. Most insurance companies refer to *voice therapy* as *speech therapy*, but they are the same thing if provided by a certified and licensed SLP.

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