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Clinical Practice Guideline: Acute Otitis Externa Executive Summary

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Abstract

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) has published a supplement to this issue featuring the updated Clinical Practice Guideline: Acute Otitis Externa, as a supplement to *Otolaryngology–Head and Neck Surgery*. To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 8 recommendations developed address appropriate diagnosis of acute otitis externa (AOE) and the use of oral and topical antimicrobials and highlight the need for adequate pain relief. An updated guideline is needed due to new clinical trials, new systematic reviews, and the lack of consumer participation in the initial guideline development group.

Keywords

acute otitis externa, clinical practice guideline, topical antimicrobial therapy, randomized controlled trials, meta-analysis

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Introduction

The Clinical Practice Guideline: Acute Otitis Externa is intended for primary care and specialist clinicians, including otolaryngologist–head and neck surgeons, pediatricians, family physicians, emergency physicians, internists, nurse-practitioners, and physician assistants. The target patient is aged 2 years or older with diffuse acute otitis externa (AOE). Differential diagnosis is discussed, but recommendations for management are limited to diffuse AOE, which is almost exclusively a bacterial infection. The recommendations developed address appropriate diagnosis of AOE and the use of oral and topical antimicrobials and highlight the need for adequate pain relief. The guideline is applicable in any setting in which patients with diffuse AOE would be identified, monitored, or managed. Recommendations in a guideline can only be implemented if they are clear and identifiable. This goal is best achieved by structuring the guideline around a series of *key action statements*, which are supported by amplifying text and action statement profiles. For ease of reference only the statements and profiles are included in this brief summary. Please refer to the complete guideline for the important information in the amplifying text that further explains the supporting evidence and details of implementation for each key action statement.

Differences from Prior Guideline

This clinical practice guideline is as an update, and replacement, for an earlier guideline published in 2006 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation.[1] Changes in content and methodology from the prior guideline include:

- addition of a dermatologist and consumer advocate to the guideline development group;
- expanded action statement profiles to explicitly state confidence in the evidence, intentional vagueness, and differences of opinion;
- enhanced external review process to include public comment and journal peer review;
- new evidence from 12 randomized, controlled trials and 2 systematic reviews;
- review and update of all supporting text;
- emphasis on patient education and counseling with new tables that list common questions with clear, simple answers and provide instructions for properly administering ear drops.

Background

AOE as discussed in this guideline is defined as diffuse inflammation of the external ear canal, which may also involve the pinna or tympanic membrane. A diagnosis of diffuse AOE requires rapid onset (generally within 48 hours) in the past 3 weeks of symptoms and signs of ear

canal inflammation as detailed in **Table 1**. A hallmark sign of diffuse AOE is tenderness of the tragus, pinna, or both that is often intense and disproportionate to what might be expected based on visual inspection.

AOE is a cellulitis of the ear canal skin and subdermis, with acute inflammation and variable edema. Nearly all (98%) AOE in North America is bacterial.[2] The most common pathogens are *Pseudomonas aeruginosa* (20%-60% prevalence) and *Staphylococcus aureus* (10%-70% prevalence), often occurring as a polymicrobial infection. Other pathogens are principally Gram-negative organisms (other than *P. aeruginosa*), any one of which cause no more than 2% to 3% of cases in large clinical series.[3-10] Fungal involvement is distinctly uncommon in primary AOE but may be more common in chronic otitis externa or after treatment of AOE with topical, or less often systemic, antibiotics.[11]

The primary outcome considered in this guideline is clinical resolution of AOE, which implies resolution of all presenting signs and symptoms (eg, pain, fever, otorrhea). Additional outcomes considered include minimizing the use of ineffective treatments; eradicating pathogens; minimizing recurrence, cost, complications, and adverse events; maximizing the health-related quality of life of individuals afflicted with AOE; increasing patient satisfaction;[12] and permitting the continued use of necessary hearing aids. The relatively high incidence of AOE and the diversity of interventions in practice make AOE an important condition for the use of an up-to-date, evidence-based practice guideline.

Table 1. Elements of the diagnosis of diffuse acute otitis externa.

1. Rapid onset (generally within 48 hours) in the past 3 weeks, AND…
2. Symptoms of ear canal inflammation, which include: otalgia (often severe), itching, or fullness, WITH OR WITHOUT hearing loss or jaw pain,[a] AND…
3. Signs of ear canal inflammation, which include: tenderness of the tragus, pinna, or both OR diffuse ear canal edema, erythema, or both WITH OR WITHOUT otorrhea, regional lymphadenitis, tympanic membrane erythema, or cellulitis of the pinna and adjacent skin

[a]Pain in the ear canal and temporomandibular joint region intensified by jaw motion.

Purpose

The primary purpose of the original guideline was to promote appropriate use of oral and topical antimicrobials for AOE and to highlight the need for adequate pain relief. An updated guideline is needed because of new clinical trials, new systematic reviews, and the lack of consumer participation in the initial guideline development group. The target patient is aged 2 years or older with diffuse AOE, defined as generalized inflammation of the external ear canal, with or without involvement of the pinna or tympanic membrane. This guideline does not apply to children under age 2 years or to patients of any age with chronic or malignant (progressive necrotizing) otitis externa. AOE is uncommon before age 2 years, and very limited evidence exists regarding treatment or outcomes in this age group.[13] Although the differential diagnosis of the ''draining ear'' will be discussed, recommendations for management will be limited to diffuse AOE, which is almost exclusively a bacterial infection. The following conditions will be briefly discussed but not considered in detail: furunculosis (localized AOE), otomycosis, herpes zoster oticus (Ramsay Hunt syndrome), and contact dermatitis.

The guideline is intended for primary care and specialist clinicians, including otolaryngologist–head and neck surgeons, pediatricians, family physicians, emergency physicians, internists, nurse-practitioners, and physician assistants. The guideline is applicable to any setting in which children, adolescents, or adults with diffuse AOE would be identified, monitored, or managed.

Methods

This guideline was developed following the methodology for updating guidelines detailed in the AAO-HNSF's guideline development manual.[14] Members of the panel represented the disciplines of otolaryngology–head and neck surgery, pediatrics, infectious disease, family medicine, dermatology, and a consumer advocate. For additional details on the methodology, please refer to the complete text of the guideline.[15] The 8 guideline recommendations are summarized in **Table 2**, with the corresponding action statements and profiles reproduced in the following. Supporting text and complete citations can be found in the guideline proper.[15]

Key Action Statements

STATEMENT 1. DIFFERENTIAL DIAGNOSIS: Clinicians should distinguish diffuse AOE from other causes of otalgia, otorrhea, and inflammation of the

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external ear canal. *Recommendation based on observational studies with a preponderance of benefit over risk.*

Action Statement Profile

- Aggregate evidence quality: Grade C, observational studies and Grade D, reasoning from first principles
- Level of confidence in evidence: high
- Benefit: improved diagnostic accuracy
- Risks, harms, costs: none in following the recommended action
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: importance of accurate diagnosis
- Intentional vagueness: none
- Role of patient preferences: none, regarding the need for a proper diagnosis
- Exceptions: none
- Policy level: recommendation
- Differences of opinion: none

STATEMENT 2. MODIFYING FACTORS: Clinicians should assess the patient with diffuse AOE for factors that modify management (non-intact tympanic membrane, tympanostomy tube, diabetes, immunocompromised state, prior radiotherapy). *Recommendation based on observational studies with a preponderance of benefit over risk.*

Action Statement Profile

- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in evidence: high
- Benefit: optimizing treatment of AOE through appropriate diagnosis and recognition of factors or comorbid conditions that might alter management
- Risks, harms, costs: none from following the recommendation; additional expense of diagnostic tests or imaging studies to identify modifying factors
- Benefits-harm assessment: preponderance of benefits over harm
- Value judgments: avoiding complications that could potentially be prevented by modifying the management approach based on the specific factors identified
- Intentional vagueness: none
- Role of patient preferences: none
- Exceptions: none
- Policy level: recommendation
- Differences of opinion: none

STATEMENT 3. PAIN MANAGEMENT: The clinician should assess patients with AOE for pain and recommend analgesic treatment based on the severity of pain. *Strong recommendation based on well-designed randomized trials with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, one randomized controlled trial limited to AOE; consistent, well-designed randomized trials of analgesics for pain relief in general
- Level of confidence in evidence: high
- Benefit: increase patient satisfaction, allow faster return to normal activities
- Risks, harms, costs: adverse effects of analgesics; direct cost of medication
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: consensus among guideline development group that the severity of pain associated with AOE is under-recognized; preeminent role of pain relief as an outcome when managing AOE
- Intentional vagueness: none
- Role of patient preferences: moderate, choice of analgesic and degree of pain tolerance
- Exceptions: none
- Policy level: strong recommendation
- Differences of opinion: none

STATEMENT 4. SYSTEMIC ANTIMICROBIALS: Clinicians should not prescribe systemic antimicrobials as initial therapy for diffuse, uncomplicated AOE unless there is extension outside the ear canal or the presence of specific host factors that would indicate a need for systemic therapy. *Strong recommendation based on randomized controlled trials with minor limitations and a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, randomized controlled trials with minor limitations; no direct comparisons of topical versus systemic therapy
- Level of confidence in evidence: high
- Benefit: avoid side effects from ineffective therapy, reduce antibiotic resistance by avoiding systemic antibiotics
- Risks, harms, costs: none
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: desire to decrease the use of ineffective treatments, societal benefit from avoiding the development of antibiotic resistance
- Intentional vagueness: none

Table 2. Summary of evidence-based statements.

Statement	Action	Strength
1. Differential diagnosis	Clinicians should distinguish diffuse acute otitis externa (AOE) from other causes of otalgia, otorrhea, and inflammation of the external ear canal.	Recommendation
2. Modifying factors	Clinicians should assess the patient with diffuse AOE for factors that modify management (non-intact tympanic membrane, tympanostomy tube, diabetes, immunocompromised state, prior radiotherapy)	Recommendation
3. Pain management	The clinician should assess patients with AOE for pain and recommend analgesic treatment based on the severity of pain.	Strong recommendation
4. Systemic antimicrobials	Clinicians should not prescribe systemic antimicrobials as initial therapy for diffuse, uncomplicated AOE unless there is extension outside the ear canal or the presence of specific host factors that would indicate a need for systemic therapy.	Strong recommendation
5. Topical therapy	Clinicians should use topical preparations for initial therapy of diffuse, uncomplicated AOE.	Recommendation
6. Drug delivery	The clinician should inform patients how to administer topical drops and should enhance delivery of topical drops when the ear canal is obstructed by performing aural toilet, placing a wick, or both.	Recommendation
7. Non-intact tympanic membrane	When the patient has a known or suspected perforation of the tympanic membrane, including a tympanostomy tube, the clinician should recommend a non-ototoxic topical preparation.	Recommendation
8. Outcome assessment	If the patient fails to respond to the initial therapeutic option within 48-72 hours the clinician should reassess the patient to confirm the diagnosis of diffuse AOE and to exclude other causes of illness.	Recommendation

- Role of patient preferences: none
- Exceptions: none
- Policy level: strong recommendation
- Differences of opinion: none

STATEMENT 5. TOPICAL THERAPY: Clinicians should prescribe topical preparations for initial therapy of diffuse, uncomplicated AOE. *Recommendation based on randomized trials with some heterogeneity and a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, meta-analyses of randomized controlled trials with significant limitations and heterogeneity
- Level of confidence in evidence: high for the efficacy of topical therapy as initial management, but low regarding comparative benefits of different classes of drugs or combinations of ototopical drugs
- Benefit: effective therapy, low incidence of adverse events
- Risks, harms, costs: direct cost of medication (varies greatly depending on drug class and selection), risk of secondary fungal infection (otomycosis) with prolonged use of topical antibiotics
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: randomized controlled trial (RCT) results from largely specialty settings may not be generalizable to patients seen in primary care settings, where the ability to perform effective aural toilet may be limited
- Intentional vagueness: no specific recommendations regarding the choice of ototopical agent
- Role of patient preferences: substantial role for patient preference in choice of topical therapeutic agent
- Exceptions: patients with a non-intact tympanic membrane (see Statement #7 on ''Non-intact tympanic membrane)
- Policy level: recommendation
- Differences of opinion: none

The purpose of this statement is to emphasize the importance of topical therapy, without systemic antibiotics, for initial management of uncomplicated AOE. A variety of topical preparations are approved by the US Food and Drug Administration (FDA) for treating AOE (***Table 3***). *Patient education is important to maximize adherence to therapy when eardrops are prescribed as initial therapy for AOE.* ***Table 4*** *summarizes frequently asked questions from patients and provides suggested responses for counseling and* ***Table 5*** *summarizes instructions for patients.*

Table 3. Common topical otic preparations approved by the FDA for treating diffuse acute otitis externa (AOE).

Active drug(s)	Name	Bottle size, ml	Cost, US$[a]	
			Trade	Generic
Acetic acid 2.0% solution	Acetic acid otic (generic)	15.0	—	33
Acetic acid 2.0%, hydrocortisone 1.0%	Acetasol HC (generic)	10.0	—	23
Ciprofloxacin 0.2%, hydrocortisone 1.0%	Cipro HC (trade)	10.0	170	—
Ciprofloxacin 0.3%, dexamethasone 0.1%	Ciprodex (trade)	7.5	144	—
Neomycin, polymyxin B, hydrocortisone	Cortisporin Otic (trade)	10.0	85	30
Ofloxacin 0.3%	Floxin Otic (trade)	5.0	76	18

[a]Approximate price in New York metropolitan region.[16]

STATEMENT 6. DRUG DELIVERY: The clinician should enhance the delivery of topical drops by informing the patient how to administer topical drops and by performing aural toilet, placing a wick, or both, when the ear canal is obstructed. *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, observational studies and Grade D, first principles
- Level of confidence in evidence: high
- Benefit: improved adherence to therapy and drug delivery
- Risks, harms, costs: pain and local trauma caused by inappropriate aural toilet or wick insertion; direct cost of wick (inexpensive)
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: despite an absence of RCTs demonstrating a benefit of aural toilet, the guideline development group agreed that cleaning was appropriate, when necessary, to improve penetration of the drops into the ear canal
- Intentional vagueness: none
- Role of patient preferences: choice of self-administering drops versus using assistant
- Exceptions: none
- Policy level: recommendation
- Differences of opinion: none

STATEMENT 7. NON-INTACT TYMPANIC MEMBRANE. When the patient has a known or suspected perforation of the tympanic membrane, including a tympanostomy tube, the clinician should prescribe a non-ototoxic topical preparation. *Recommendation based on reasoning from first principles and on exceptional circumstances where validating studies cannot be performed a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade D, reasoning from first principles, and Grade X, exceptional situations where validating studies cannot be performed
- Level of confidence in evidence: moderate, because of extrapolation of data from animal studies and little direct evidence in patients with AOE
- Benefit: reduce the possibility of hearing loss and balance disturbance
- Risk, harm, cost: eardrops without ototoxicity may be more costly
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: importance of avoiding iatrogenic hearing loss from a potentially ototoxic topical preparation when non-ototoxic alternatives are available; placing safety above direct cost
- Intentional vagueness: none
- Role of patient preferences: none
- Exceptions: none
- Policy level: recommendation
- Differences of opinion: none

STATEMENT 8. OUTCOME ASSESSMENT: The clinician should reassess the patient who fails to respond to the initial therapeutic option within 48 to 72 hours to confirm the diagnosis of diffuse AOE and to exclude other causes of illness. *Recommendation based on observational studies and a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, outcomes from individual treatment arms of randomized controlled trials of efficacy of topical therapy for AOE
- Level of confidence in evidence: medium, because most randomized trials have been conducted in specialist settings and the generalizability to primary care settings is unknown

Table 4. Patient information for topical therapy of acute otitis externa (AOE).

Frequently asked question	Answer
Are eardrops alone sufficient to treat my infection or do I also need to take an antibiotic by mouth?	Eardrops alone are the most effective treatment for AOE and may contain antibiotics, antiseptics, steroids, or a combination. Antibiotics taken by mouth do not kill most germs that cause AOE and should be used only when infection spreads beyond the ear canal, eardrops cannot get into the ear, or the immune system is weak.
Which eardrop is best for treating my ear infection?	All eardrops approved for treating AOE (**Table 5**) are highly effective with no consistent advantage shown for any one specific drug.
If all eardrops are equally effective, why do doctors prescribe different ones?	Your doctor will discuss with you the reasoning behind his or her eardrop recommendation, but some of the factors considered include cost, dosing frequency, status of the eardrum, and the doctor's experience. Your opinion and preferences should also factor into this decision.
Is there anything I should be sure to tell my doctor that might help in deciding which eardrop is best?	Let your doctor know if you had any prior ear surgery, if there is an opening (hole or perforation) of the eardrum, or if an ear tube is in place. If one or more of these conditions apply then your doctor will need to use an eardrop that is approved for use in the middle ear, just in case some of it gets past the eardrum. Also let your doctor know if you have recently used other ear products or medications or if you have had a reaction in the past to a particular eardrop or antibiotic. Last, tell your doctor if you have, or are suspected to have, diabetes, since this could alter management.
Once I start using the eardrops how long should it take until I feel better?	Most people feel better within 48 to 72 hours and have minimal or no symptoms by 7 days. Notify your doctor if your pain or other symptoms fail to respond within this timeframe.
If it usually takes at least 48 hours to feel better from the eardrops what should I do for earlier relief?	Pain medicine is especially important to use for relief in the first few days, until the eardrops begin working. Discuss with your doctor which pain medicines are best for you. Pain-relieving (anesthetic) eardrops are not recommended because they are not intended for use during an active ear canal infection and can mask symptoms of a delayed response to therapy.
For how long will I need to use the eardrops?	Eardrops should be used for at least 7 days, even if you feel better sooner, to prevent relapse of infection. If symptoms persist beyond 7 days you should notify your doctor and continue the drops until the symptoms resolve for a maximum of 7 additional days.
Are there any activity restrictions or special precautions that will help my ear recover faster?	Avoid scratching or touching the ear and do not insert anything into the ear canal, including cotton-tipped swabs. Cover the opening of ear canal with an earplug or cotton (with petroleum jelly) prior to showering or hair washing to minimize water entry. Check with your doctor regarding swimming or other water activities that may take place during, or soon after, your infection.
Do eardrops have side effects that I should be aware of?	Eardrops are, in general, very safe and well tolerated. Some people report local rash, itching, irritation, or discomfort, but it is rarely bad enough to require stopping the medication. If you taste the eardrops it means there is likely a hole or perforation of the eardrum, so inform your doctor (if you have not already done so). Also call your doctor if the drops become painful or you develop unexpected symptoms.

- Benefit: identify misdiagnosis and potential complications from delayed management; reduce pain
- Risks, harms, costs: cost of reevaluation by clinician
- Benefits-harms assessment: preponderance of benefit over harm
- Value judgments: none
- Intentional vagueness: timeframe of 48 to 72 hours is specified since there are no data to substantiate a more precise estimate of time to improvement
- Role of patient preferences: none
- Exceptions: none
- Policy level: recommendation
- Differences of opinion: none

Disclaimer

This clinical practice guideline is provided for information and education purposes only. It is not intended as a sole source of guidance in managing patients with acute otitis externa. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. This guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this

Table 5. Instructions for patients.

- If possible get someone to put the drops in the ear canal for you.
- Lie down with the affected ear up. Put enough drops in the ear canal to fill it up.
- Once the drops are in place, stay in this position for 3 to 5 minutes. Use a timer to help measure the time. It is important to allow adequate time for the drops to penetrate into the ear canal.
- A gentle to-and-fro movement of the ear will sometimes help in getting the drops to their intended destination. An alternate method is to press with an in/out movement on the small piece of cartilage (tragus) in front of the ear.
- You may then get up and resume your normal activities. Wipe off any excess drops.
- Keeping the ear dry is generally a good idea while using ear drops.
- Try not to clean the ear yourself as the ear is very tender and you could possibly damage the ear canal or even the eardrum.
- If the drops do not easily run into the ear canal you may need to have the ear canal cleaned by your clinician or have a wick placed in the ear canal to help in getting the drops into the ear canal
- If you do have a wick placed, it may fall out on its own. This is a good sign as it means the inflammation is clearing and the infection subsiding.
- Do not remove the wick yourself unless instructed to do so.

condition and may not provide the only appropriate approach to diagnosis and management.

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 the 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 American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results.

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