



Complete Summary

GUIDELINE TITLE

Clinical practice guideline: acute otitis externa.

BIBLIOGRAPHIC SOURCE(S)

Rosenfeld RM, Brown L, Cannon CR, Dolor RJ, Ganiats TG, Hannley M, Kokemueller P, Marcy SM, Roland PS, Shiffman RN, Stinnett SS, Witsell DL, American Academy of Otolaryngology--Head and Neck Surgery Foundation. Clinical practice guideline: acute otitis externa. *Otolaryngol Head Neck Surg* 2006 Apr;134(4 Suppl):S4-23. [137 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

Diffuse acute otitis externa (AOE), defined as generalized inflammation of the external ear canal, with or without involvement of the pinna or tympanic membrane

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Infectious Diseases
Internal Medicine
Otolaryngology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations to manage diffuse acute otitis externa (AOE)
- To promote appropriate use of oral and topical antimicrobials and to highlight the need for adequate pain relief

TARGET POPULATION

Patients aged 2 years or older with diffuse acute otitis externa (AOE)

Note: 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 with respect to treatment or outcomes in this age group.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. History and physical examination
2. Otoscopy
3. Pneumatic otoscopy
4. Otomicroscopy
5. Tympanometry
6. Acoustic reflectometry
7. Culture
8. Imaging studies
9. Audiometry (excluded from guideline)

Treatment/Management

1. Aural toilet (suction, dry mopping, irrigation, removal of obstructing cerumen or foreign object)
2. Nonantibiotic (antiseptic or acidifying) drops
3. Antibiotic drops

4. Steroid drops
5. Oral antibiotics
6. Analgesics (after assessment of pain)
7. Complementary and alternative medicine
8. Ear canal wick
9. Biopsy (excluded from guideline)
10. Surgery (excluded from guideline)

Prevention

1. Water precautions
2. Prophylactic drops
3. Environmental control (e.g., hot tubs)
4. Avoiding neomycin drops (if allergic)
5. Addressing allergy to ear molds or water protector
6. Addressing underlying dermatitis
7. Specific preventive measures for diabetics or immunocompromised state

MAJOR OUTCOMES CONSIDERED

- Clinical resolution of acute otitis externa (AOE)
- Minimized use of ineffective treatments
- Eradication of pathogens
- Minimized recurrence, cost, complications, and adverse events
- Quality of life
- Patient satisfaction
- Continued hearing aid use

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A MEDLINE search from 1966 through July 2005 was performed on PubMed with the terms "otitis externa" (MeSH term) and "swimmer's ear." Titles and abstracts unrelated to acute otitis externa (AOE) were excluded, leaving 240 articles that were collated under these headings: risk factors (n=30), microbiology (n=24), pharmacologic intervention (n=118), other interventions (n=17), epidemiology and practice patterns (n=14), potential harms (n=30), and otomycosis (n=9). Citations and abstracts were distributed to all group members to assist in formulating and prioritizing evidence-based statements. Members performed additional targeted MEDLINE searches through September 2005 to supplement the initial broad search.

Systematic Review of Topical Antimicrobial Therapy

A systematic review of topical antimicrobial therapy for AOE was performed with the goal to identify relevant randomized controlled trials (RCTs) and derive summary estimates of effect size by statistically pooling data from similar studies.

An electronic MEDLINE search from 1966 through July 2005 for AOE articles was performed with the use of a search strategy adapted from a Cochrane protocol. The resulting set of 2860 articles was limited to 509 with a maximally sensitive strategy to find clinical trials suitable for meta-analysis. Electronic search of the Cochrane Registry of Clinical Trials with "otitis externa OR external otitis OR swimmer's ear" identified studies, of which 7 were unique. CINAHL search from 1982 through July 2005 did not identify any unique studies. Titles and abstracts of the initial data set were scanned for parallel group RCTs of topical therapy for diffuse AOE. Articles were excluded if they were not about a clinical trial, had only a single treatment group, or dealt with otorrhea caused by conditions other than diffuse AOE (e.g., otomycosis, tympanostomy tube otorrhea, middle-ear disease, eczematous or malignant otitis externa). The remaining initial data set contained 43 articles.

Two independent reviewers assessed the initial data set for articles that were limited to diffuse AOE (or had subgroup data for diffuse AOE) and had 2 or more parallel treatment groups that permitted 1 or more of the following topical drug comparisons: antimicrobial vs placebo; antiseptic vs antimicrobial; quinolone antibiotic vs nonquinolone antibiotic; steroid-antimicrobial vs antimicrobial; and antimicrobial-steroid vs steroid.

NUMBER OF SOURCE DOCUMENTS

240 articles on acute otitis externa (general search)
20 articles on topical antimicrobial therapy for acute otitis externa

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Quality for Grades of Evidence

Grade A: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review of Topical Antimicrobial Therapy

Quality of the 20 articles obtained from literature searches was assessed with the Jadad scale, which awards a maximum of 5 points based on randomization, masking, withdrawals, and dropouts. The Jadad scale was used for descriptive purposes and to see how study results varied by quality score.

Two independent reviewers abstracted data for the 20 articles with a standardized form. Descriptive information included the definition of acute otitis externa (AOE), inclusion criteria, exclusion criteria, sample demographics, frequency and method of aural toilet, use of a wick for drug delivery, and patient compliance with treatment. Quantitative information included number of subjects at trial start, number of withdrawals by group, adverse events by group, clinical outcomes by group, and bacteriologic outcomes by group. Any disagreement or inconsistency among data obtained by the reviewers for a given article was resolved after mutual discussion with a third reviewer.

Clinical outcomes were defined as "cured" (absence of all presenting signs and symptoms of diffuse AOE) or "improved" (partial or complete relief of presenting signs and symptoms). Binary outcomes were emphasized (e.g., cured vs. not cured, improved vs. not improved, bacteriologic cure vs. failure), but continuous outcomes were recorded when present (e.g., mean days of otorrhea, mean days of otalgia). Clinical binary outcomes were recorded by time point, and were anticipated to be roughly combinable as early response at 3 to 4 days, end-of-therapy response at 7 to 13 days, and test-of-cure at 14 to 21 days. Final time points for the combined analysis would be determined based on data availability for each specific comparison. Bacteriologic response was not recorded by time point because no study gave more than 1 outcome.

Data from individual studies were combined (pooled) whenever results were available from 2 or more source articles for a particular endpoint and outcome time. Although reviewers initially planned on using the intent-to-treat (ITT) denominator in all analyses, they instead used the per-protocol denominator because only 4 studies reported ITT data. The unit of analysis was patients, but 2 antiseptic studies reporting outcomes by ears were included because 90% or more of subjects had unilateral AOE. Two other studies could not be combined because they reported only time to symptom resolution and did not report any binary clinical or bacteriologic outcomes.

If a study contained more than 2 parallel treatment groups, only the 2 groups most relevant to the hypothesis being tested were used. For example, a study

with the treatment groups (A) acetic acid, (B) acetic acid + triamcinolone, and (C) neomycin + polymyxin B + dexamethasone could be used to test the hypotheses antiseptic vs antimicrobial (B vs. C) and steroid-antimicrobial vs antimicrobial (B vs. A). The first comparison is made with groups B vs C instead of B vs. A, because both groups contain a steroid. Even though the steroid is not exactly the same in both groups, this is more relevant to the hypothesis being tested than a comparison in which only 1 group had a steroid.

Statistical pooling was done with a random-effects model of meta-analysis that assumes a population (distribution) of true effect sizes with each source article representing 1 member of this population. Under this model, results are expected to vary from study to study, with differences caused by experimental error and differences in populations (between-study variability). Because of this additional variability, the 95% confidence interval (CI) for the pooled result is wider (less precise) than for a fixed-effect model.

Statistical analysis was performed with the Comprehensive Meta-Analysis, which weights study results by the inverse of variance and calculates a random effects estimate of the combined effect and 95% CI. A test of heterogeneity is performed with the Q statistic to evaluate constancy of effect across strata. Significant heterogeneity exists if $P < 0.05$, although the test has low power and important variations may be present even with a nonsignificant result. For this reason, the random effects model is used regardless of the test of heterogeneity, although test results are still stated which ranges from 0% to 100% and describes the percentage of total variation across studies caused by heterogeneity (25% is low, 50% moderate, 75% high).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 7 months devoted to guideline development ending in November 2005, the group met twice with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

In September and November 2005, the Guidelines Review Group of the Yale Center for Medical Informatics used GEM-COGS, the Guideline Implementability Appraisal (GLIA) and Extractor software, to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Acute otitis externa (AOE) guideline development group members received summary appraisals before their second meeting and modified an advanced draft of the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means 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)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication:* Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication:* Clinicians also should 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)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another. *Implication:* 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.

No Recommendation: No recommendation means that there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms. *Implication:* Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

* Refer to "Rating Scheme for the Strength of the Evidence" field above for the definitions of evidence grades.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final draft practice guideline underwent extensive external peer review. Comments were compiled and reviewed by the group chairperson.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grades (A-D) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are repeated at the end of the "Major Recommendations" field.

1a. Differential Diagnosis: Clinicians should distinguish diffuse acute otitis externa (AOE) from other causes of otalgia, otorrhea, and inflammation of the external ear canal.

(Recommendation based on observational studies with a preponderance of benefit over risk).

*Aggregate evidence quality: **C**, observational studies and **D**, expert opinion*

*Policy level: **recommendation***

1b. Modifying Factors: Clinicians should assess the patient with diffuse AOE for factors that modify management (nonintact tympanic membrane, tympanostomy tube, diabetes, immunocompromised state, prior radiotherapy).

(Recommendation based on observational studies with a preponderance of benefit over risk).

*Aggregate evidence quality: **C**, observational studies*

*Policy level: **recommendation***

2. Pain Management: The management of diffuse AOE should include an assessment of pain. The clinician should recommend analgesic treatment based on the severity of pain.

(Strong recommendation based on well-designed randomized trials with a preponderance of benefit over harm).

*Aggregate evidence quality: **B**, 1 randomized controlled trial limited to AOE; consistent, well-designed randomized trials of analgesics for pain relief in general*

*Policy level: **strong recommendation***

3. Initial Therapy: Clinicians should use topical preparations for initial therapy of diffuse, uncomplicated AOE. Systemic antimicrobial therapy should not be used unless there is extension outside the ear canal or the presence of specific host factors that would indicate a need for systemic therapy.

(Recommendation based on randomized controlled trials with minor limitations and a preponderance of benefit over harm).

*Aggregate evidence quality: **B**, randomized controlled trials with minor limitations; no direct comparisons of topical vs systemic therapy*

*Policy level: **recommendation***

4. Topical Therapy: The choice of topical antimicrobial for initial therapy of diffuse AOE should be based upon efficacy, low incidence of adverse events, likelihood of adherence to therapy, and cost.

(Recommendation based on randomized trials with some heterogeneity and a preponderance of benefit over harm).

*Aggregate evidence quality: **B**, randomized controlled trials with some heterogeneity*

*Policy level: **recommendation***

5. Drug Delivery: Clinicians should inform patients how to administer topical drops. When the ear canal is obstructed, delivery of topical preparations should be enhanced by aural toilet, placement of a wick, or both.

(Recommendation based on observational studies with a preponderance of benefit over harm).

*Aggregate evidence quality: **C**, observational studies and **D**, expert opinion*

*Policy level: **recommendation***

6. Non-Intact Tympanic Membrane: When the patient has a tympanostomy tube or known perforation of the tympanic membrane, 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 and there is clear preponderance of benefit over harm).

*Aggregate evidence quality: **D**, reasoning from first principles, and **X**, exceptional situations where validating studies cannot be performed*

*Policy level: **recommendation***

7. Outcome Assessment: If the patient fails to respond to the initial therapeutic option within 48 to 72 hours, the clinician should reassess the patient 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).

*Aggregate evidence quality: **C**, observational studies*

Policy level: **recommendation**

Definitions:

Guideline Definitions for Evidence-Based Statements

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Evidence Quality for Grades of Evidence

Grade A: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for managing acute otitis externa.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations contained in the practice guideline are based on the best available published data through September 2005. Where data are lacking, a combination of clinical experience and expert consensus was used. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Differential diagnosis: improved diagnostic accuracy
- Modifying factors: optimizing treatment of acute otitis externa (AOE) through appropriate diagnosis and recognition of modifying factors
- Pain management: increase patient satisfaction, allows faster return to normal activities
- Initial therapy: avoid side effects by not using unnecessary systemic medications, avoid increased disease persistence rates and disease recurrence rates seen when inappropriate systemic antibiotics are used, reduce antibiotic resistance by avoiding systemic antibiotics, and potential for increased patient adherence to therapy
- Topical therapy: effective therapy, appropriate adherence to therapy, and acceptable cost
- Drug delivery: improved adherence to therapy and drug delivery
- Non-intact tympanic membrane: avoid pain and hearing loss
- Outcome assessment: identify misdiagnosis and potential complications from delayed management; reduce pain

POTENTIAL HARMS

- Differential diagnosis: none
- Modifying factors: none
- Pain management: adverse effects of analgesics
- Initial therapy: adverse effects of topical antimicrobials
- Topical therapy: low incidence of adverse events
- Drug delivery: pain and local trauma caused by inappropriate aural toilet or wick insertion
- Non-intact tympanic membrane: none
- Outcome assessment: none

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This clinical practice guideline is not intended as a sole source of guidance in evaluating patients with acute otitis externa (AOE). Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. It 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 the diagnosis and management of this problem.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation Considerations

The complete guideline is published as a supplement to Otolaryngology-Head and Neck Surgery to facilitate reference and distribution. A full-text version of the guideline will also be accessible free of charge at the www.entnet.org, the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) website. The AAO-HNSF has also given permission for members of the working group to have their professional medical societies publish all or part of the guideline in their journals or in electronic form. The guideline will be presented to AAO-HNSF members as a miniseminar at the annual meeting after publication. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

Anticipated barriers to application of the recommendations in the guideline include: 1) difficulty of changing ingrained clinician habits toward prescribing ineffective systemic therapy for acute otitis externa (AOE), 2) inability or unwillingness of some clinicians to perform aural toilet or insert a wick into the ear canal, and 3) cost of some topical medications, especially the quinolone products recommended for use with a nonintact tympanic membrane. The first 2 can be addressed with educational events and workshops at continuing medical education events. The issue of cost should become less problematic in the next few years as generic versions of the quinolone otic drops become available.

The impact of the guideline on clinical practice will be assessed for otolaryngologists when a performance measure is developed. As noted above, one purpose of developing the guideline was to facilitate creation of a performance measure for maintenance of certification in otolaryngology-head and neck

surgery. The guideline working group did not specifically discuss measuring impact on clinicians other than otolaryngologists.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rosenfeld RM, Brown L, Cannon CR, Dolor RJ, Ganiats TG, Hannley M, Kokemueller P, Marcy SM, Roland PS, Shiffman RN, Stinnett SS, Witsell DL, American Academy of Otolaryngology--Head and Neck Surgery Foundation. Clinical practice guideline: acute otitis externa. Otolaryngol Head Neck Surg 2006 Apr;134(4 Suppl):S4-23. [137 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Otolaryngology--Head and Neck Surgery Foundation

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Richard M. Rosenfeld, MD, MPH; Lance Brown, MD, MPH; C. Ron Cannon, MD; Rowena J. Dolor, MD, MHS; Theodore G. Ganiats, MD; Maureen Hannley, PhD; Phillip Kokemueller, MS, CAE; S. Michael Marcy, MD; Peter S. Roland, MD; Richard N. Shiffman, MD, MCIS; Sandra S. Stinnett, DrPH; David L. Witsell, MD, MHS

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Alcon Laboratories provided an unrestricted educational grant to the American Academy of Otolaryngology-Head and Neck Surgery Foundation to create an acute otitis externa (AOE) performance measure and clinical practice guideline. The sponsor had no involvement in any aspect of developing the guideline and was unaware of content until publication. Individual disclosures for group members are: RM Rosenfeld, past consultant to Alcon Laboratories and Daiichi Pharmaceuticals; and PS Roland, speaking honoraria, departmental consulting fees for research support from Alcon Laboratories and Daiichi Pharmaceuticals. SM Marcy is a consultant for Medimmune, Merck, Sanofi - Pasteur, and GlaxoSmithKline. No other panel members had disclosures. Disclosures were made available to the Guideline Development Group for open discussion, with the conclusion that none of the relationships would preclude participation.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of the [Otolaryngology - Head and Neck Surgery](#) journal.

Print copies: Available from Richard M. Rosenfeld, MD, MPH, Department of Otolaryngology, 339 Hicks Street, Brooklyn, NY 11201-5514; E-mail: richrosenfeld@msn.com

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Rosenfeld RM, Singer M, Wasserman JM, Stinnett SS, Witsell DL. Systematic review of topical antimicrobial therapy for acute otitis externa. *Otolaryngol Head Neck Surg* 2006 Apr;134:S24-48. Electronic copies: Available to subscribers of the [Otolaryngology - Head and Neck Surgery](#) journal.

PATIENT RESOURCES

None available

NGC STATUS

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