Complete Summary

GUIDELINE TITLE

Diagnosis and management of childhood otitis media in primary care. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no. 66). [77 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 2003 and will be considered for review as new evidence becomes available.

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Acute otitis media
- Otitis media with effusion

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Otolaryngology
Pediatrics
Speech-Language Pathology

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments
Social Workers
Speech-Language Pathologists

GUIDELINE OBJECTIVE(S)

- To provide recommendations based on current evidence for best practice in the management of acute otitis media and otitis media with effusion
- To provide evidence about detection, management, referral and follow-up of children with acute otitis media and otitis media with effusion

Note: This guideline excludes discussion of surgical management such as the insertion of grommets and does not address issues beyond childhood years. In addition, the needs of children with genetic or facial abnormalities are not considered.

TARGET POPULATION

Children with acute otitis media or otitis media with effusion

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. History and clinical assessment, including evaluation of symptoms
2. Examination with otoscope
3. Audiometry
4. Tympanometry

Management/Treatment for Acute Otitis Media

1. Antibiotic treatment, particularly delayed antibiotic treatment

   Note: Antibiotics should not routinely be prescribed as the initial treatment.

2. Analgesics, such as paracetamol

   Note: Parents should be advised of the potential danger of overuse.

3. Follow up examination
4. Referral to otolaryngologist

Note: The following treatments should not be prescribed for children with acute otitis media: decongestants or antihistamines; oils (for pain).

Note: While homeopathy was considered, due to lack of evidence, no recommendation can be made at this time.

Management/Treatment for Otitis Media with Effusion

1. Autoinflation
2. Follow up evaluation
3. Referral to otolaryngologist

Note: The following treatments should not be used/are not recommended in the management of children with otitis media with effusion: antibiotics; decongestants; antihistamines or mucolytics; topical or systemic steroid therapy.

Note: While homeopathy was considered, due to lack of evidence, no recommendation can be made at this time.

Note: Several interventions intended for parents, teachers and caregivers were also considered, including advice on breastfeeding to reduce the incidence of otitis media; advice on smoking cessation; basic communication techniques; and advice on swimming and bathing following grommet insertion.

MAJOR OUTCOMES CONSIDERED

- Symptom resolution
- Side effects of treatment
- Speech and language, development or behavioural problems

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A thorough literature search was undertaken in Medline, Embase, and Healthstar to obtain material from 1985 to 1999 inclusive. Internet searches on key Web sites were also conducted and passed on to the group. Additional references were identified by group members and peer reviewers. All material was assessed and evidence synthesized in accordance with the Scottish Intercollegiate Guideline Network (SIGN) methodology.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Levels of Evidence

1++ - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ - Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- - Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ - High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 - Non-analytic studies, e.g., case reports, case series

4 - Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the

methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of

recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are <u>not</u> an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or randomized controlled trial rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rate as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents their draft recommendations for comment. The national open meeting for this guideline was held in November 2001 and was attended by 80 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

The guideline was then reviewed by an Editorial Group comprising relevant specialty representatives on SIGN Council, to ensure that the peer reviewers' comments had been addressed adequately and that any risk of bias in the guideline development process as a whole had been minimised.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Clinical Assessment

Diagnosis

B - Healthcare professionals should have an increased awareness of the possibility of the presence of otitis media with effusion in asymptomatic children. The following groups of children are at particular risk:

- Those in day care
- Those with older siblings
- Those with parents who smoke
- Those who present with hearing or behavioural problems

Medical Treatment

Acute Otitis Media

B - Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment.

B - Delayed antibiotic treatment (antibiotic to be collected at parents' discretion after 72 hours if the child has not improved) is an alternative approach which can be applied in general practice.

B - If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary.

A - Children with acute otitis media should not be prescribed decongestants or antihistamines.

D - Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse.

B - Insertion of oils should not be prescribed for reducing pain in children with acute otitis media.

Otitis Media with Effusion

D - Children with otitis media with effusion should not be treated with antibiotics.

B - Decongestants, antihistamines or mucolytics should not be used in the management of otitis media with effusion.

B - The use of either topical or systemic steroid therapy is not recommended in the management of children with otitis media with effusion.

D - Autoinflation may be of benefit in the management of some children with otitis media with effusion.

Follow up and Referral

Referral

D - Children with frequent episodes (more than four in six months) of acute otitis media, or complications, should be referred to an otolaryngologist.

A - Children under three years of age with persistent bilateral otitis media with effusion and hearing loss of $\leq$25 dB, but no speech and language, development or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.

B - Children with persistent bilateral otitis media with effusion who are over three years of age or who have speech language, developmental or behavioural problems should be referred to an otolaryngologist.

Patient Issues

Information for Parents, Teachers, and Carers

B - Parents of children with otitis media with effusion should be advised to refrain from smoking.

C - Parents should be advised that breastfeeding may reduce the risk of their child developing otitis media with effusion.

C - Grommet insertion is not a contraindication to swimming.

Definitions

Grades of Recommendations

A - At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or randomised controlled trial rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rate as 2++

D - Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Levels of Evidence

1++ - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ - Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- - Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ - High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 - Non-analytic studies, e.g. case reports, case series

4 - Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Antibiotics in comparison to placebo and observational treatment may have a modest benefit on symptom resolution and failure rates, as variously defined, in children over the age of two years with acute otitis media. The available evidence on natural history of acute otitis media shows that in studies with close follow up, very few episodes of mastoiditis or other suppurative complications are reported in children with acute otitis media not initially treated with antibiotics.

POTENTIAL HARMS

Acute Otitis Media

Although non-steroidal anti-inflammatory drugs (NSAIDs) are frequently used by parents, caution should be exercised because of the side effect profile.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the doctor, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. However, it is advised, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for audit are identified in the original guideline document.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

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)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no. 66). [77 references]

ADAPTATION

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

DATE RELEASED

2003 Feb

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Professor John Bain (Chairman); Dr Patricia Townsley (Secretary); Miss Karen Boyle; Mr John Dempster; Dr Ali El-Ghorr; Dr Peter Ewing; Mr Neil Geddes; Dr Ann MacKinnon; Dr Adrian Margerison; Mr William McKerrow; Dr Neil Sabiston; Dr Gavin Stark

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 2003 and will be considered for review as new evidence becomes available.

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: a guideline developers' handbook. An introduction to SIGN methodology for the development of evidence-based clinical guidelines. Edinburgh (UK): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

The following is available:

- Patient issues. In: Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no. 66).

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was prepared by ECRI on November 20, 2003. The information was verified by the guideline developer on January 16, 2004.

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