ACUTE OTITIS MEDIA

April 1998

Contents

Purpose of the Guideline

Presented here are the guideline and the working papers used in its development. This effort originated as an educational exercise for a number of Hawkes Bay GPs and practice nurses in the latter part of 1997. Subsequently, there has been some feedback from Randall Morton, Bruce Arroll and Tim Kenealy. All of this material is presented.

Clearly, the guideline is unfinished – a number of discussions have emerged from it which, to resolve, would take almost as much effort as the original work. Life and its tasks, however, moves on and I am currently not resourced with time or funds to continue this journey at this time.

One of the important lessons about guideline development work, for me, is that a satisfactory conclusion needs to be properly resourced and the work involved is much greater than would initially appear. Indeed, the draft guideline is just a beginning. However, the material and the ensuing discussion is offered in the interests of stimulating debate and in the anticipation that others will build on it.

Stuart Foote

About the Guideline

Guideline Documentation

Clinical Topic:
Treatment of acute otitis media in general practice.

Population Addressed:
General practice patients aged 2 months to 15 years, otherwise healthy, living in Western "first world" communities.

Sponsoring Body:
Hawkes Bay Independent Practitioners Association, "Paradigm"

Date of Inception:
August 1997

Most Recent Update:
August 1997

Review Date:
August 2000 or earlier if necessary

Process of Development:
The guideline development team used an explicit evidence-based process to develop the guideline and to estimate the impact on health care outcomes for the Paradigm patient population

Measurement Plan:
No system of clinical data capture is currently in place to allow regular monitoring of the management of acute otitis media.

Team Composition:
Stuart Foote, Medical Director of Paradigm, guideline convener.
Bobi Munro, Nursing Director of Paradigm.*Practice Nurses GPs Paediatrician*
Marg Estcourt, PN; Stewart Drysdale, GP; Oliver Smales, Paediatrician; Joanne Watson, consumer;
Carol Pryce, PN; Gael Donald, GP; Dixie Reo, Maori consumer;
Cheryl Pierson, PN; Liz Whyte, GP; Bev Penny, consumer;
Joanne Roe, PN; Tim O'Donovan, GP; Carol Whatuira, Maori consumer;
Liz Dixon, GP; John Kerr, GP; Peter Stormer, GP; Tim Mason, GP; Paddy O'Brien, GP

Contact Person:
Dr Stuart Foote, PO Box 2296, Stortford Lodge, Hastings.
Phone 06 870 7110, fax 06 870 7550

Guideline Information

Guideline

Early, empiric treatment of acute otitis media with antibiotics provides only modest benefit and causes a similar occurrence of antibiotic induced side effects.

It is recommended that parents of children with acute otitis media are given information about

- the benefits (NNT for less pain at 2-7 days = 17), and
- risks (NNT for vomiting, diarrhoea and rash = 17)

of antibiotic therapy. A shared decision-making approach to antibiotic therapy can then be followed.

The presence of other indications for antibiotic therapy should be taken into consideration in advising parents. Also, because of concerns about the generalisability of the evidence to Maori, Polynesian and poorer socio-economic groups, additional caution may be advised in withholding antibiotics from these groups.

If antibiotics are to be used, amoxicillin or cotrimoxazole are as effective as any other antibiotic, have a good safety profile and are cheaper. Of the two, amoxicillin may be marginally safer. Pain relief such as paracetamol or ibuprofen should be offered.

It is recommended that parents are advised to seek further advice if, after 48 hours, the child has persisting symptoms or is still unwell.

As otitis media with effusion (OME) is a consequence of and not a complication of acute otitis media, follow up in less than one month may lead to inappropriate therapy for OME. Therefore children with AOM should be reviewed in one month.

Evidence Summary

Definitions

Myringitis: Erythema of the tympanic membrane without MEE

Middle ear effusion (MEE)

- Fluid in the middle ear regardless of cause;
- Hearing loss;
- Diagnosis requires tympanometry or pneumatic otoscope

Acute otitis media (AOM): MEE with rapid onset symptoms

Recurrent otitis media (ROM): at least three episodes of AOM in past 6/12, or 4 in past 12/12.

Otitis Media with Effusion (OME): MEE without signs or symptoms of AOM

Incidence of AOM

- 1% of all patients attending NZ general practitioners include AOM as a reason for consultation.[4]
- Extrapolation of consultation rates and incidence[4] suggests 3071 presentations per year to Paradigm GPs.

Evidence of meta-analyses[5.6]

- antibiotics did not influence resolution of pain at 24 hours.
- early use of antibiotics reduced the risk of pain at 2 - 7 days by 40%.
- only 14 % of all children still have pain at 2 - 7 days, therefore benefit is to 5.6% of all children with AOM (NNT* = 17) * NNT = numbers needed to treat to benefit/harm one.
- antibiotic use reduced contralateral AOM (NNT = 17).
- antibiotic used did not influence subsequent AOM or incidence of OME.
- antibiotics increased the incidence of vomiting, diarrhoea and rash in children - for every child benefitting from reduced pain, another will suffer antibiotic induced side effects.

- broad spectrum, b Lactamase covering antibiotics conferred no advantage over cheaper drugs such as amoxicillin or co-trimoxazole.
- aggressive use of b Lactamase drugs will cause bacterial resistance.
- antibiotics for less than 7 days has no impact on efficacy.
- these results do not apply to children with serious underlying disease, OME, concomitant illness other than viral URTI or co-existing disorders requiring antibiotic therapy.

Evidence from other sources

- combining an antibiotic with an oral steroid shows promising but unproven efficacy for OME but there is no evidence of benefit in AOM.[7]
- both amoxicillin and co-trimoxazole are safe with co-trimoxazole perhaps having a marginally higher risk of serious side effects.[1-3]

Balance Sheet

Assumptions

1. The numbers of cases (3071) likely to occur in HBIPA children (0-15) is based on an assumption of 100,000 patients, age/sex demographic patterns from CRHA statistics and the same consulting rate (3.04/year) and incidence (1%) derived from the Tilyard paper 4.

2. Following the guideline is likely to have various effects on consultation rates. Some will increase consumption (increased review at 48 hours), some will decrease (fewer patients seeking medical assistance with children with sore ears, fewer recalls at one week or so, fewer inappropriate prescriptions for OME due to early recall). As there is no reliable information on these effects, no account of possible changes is attempted in this balance sheet.

3. The intuitive assessment of the incidence of acute OM by GPs on the guideline panel was that the Tilyard paper seriously underestimated the incidence. Savings made may therefore be greater by as much as 100%.

For whole of HBIPA

Outcome	Current Practice	25% antibiotic reduction	50% antibiotic reduction
Number of cases treated with a/b.	3071	2303	1535
Reduced pain at 24 hours	0	0	0
Reduced pain at 2-7 days	180	135	90
Perforations prevented *	113	85*	56*
Deafness at 1 month*	1044		
Deafness at 3 months *	644		
Contralateral AOM prevented	180	135	90
Recurrent otitis media	663	663	663
Vomiting, Diarrhoea, Rash	506	424	342
Side effects inflicted	180	135	90
Antibiotic Cost **	$24,489	$18,366	$12,244
Change mix to amoxil / cotrimox	$20,391	$15,293	$10,195
Funds released for other services	$4,098	$9,196	$14,294

* No statistically significant difference yet established.
** Based on surveyed use of antibiotics by HBIPA doctors for acute OM.

In summary

Reducing antibiotic prescribing for 3071 cases of AOM by 50% (the other 50% are assumed to have other indications for antibiotics, such as a sick child, purulent cough etc) will result in

- causing a small increase in total pain to 90 children
- possibly allowing 56 perforations to occur (not necessarily a bad thing)
- allowing 90 children to progress from unilateral to bilateral AOM
- avoiding inflicting vomiting, diarrhoea or rash on 90 children
- releasing $14,000 to be used elsewhere in the health service

Other "hidden" benefits could include:

- encouraging an "evidence based approach" amongst professionals and patients
- encouraging self reliance
- reducing a dependence on the "magic bullet" approach to health care.

Meta-Analysis

Rosenfeld et al: *Clinical efficacy of antimicrobial drugs for AOM: Meta-analysis of 5400 children from 33 RCTs*.

Study type / grade

Meta-analysis. (Grade I evidence if the meta analysis asks the same questions as ours.)

Only RCT of antibiotic vs placebo / no treatment / other antibiotic. (Therefore can potentially answer both our questions).

Studies were of empiric treatment (no bacterial identification made) of acute OM - (excluded ROM, OME, prophylaxis, etc).

Strong methodology of selection of the primary studies.

Outcomes

Primary: clinical response to antibiotics.

C complete resolution of symptoms and signs within 7 - 14/7.

C anything other than this is a primary end point failure.

Secondary: OME.

C absence of OME at 30 days.

Design

Focus on discrete clinical question? The absolute and comparative efficacy of antibiotics in AOM. (Exactly our two questions).

Explicit description of the literature search? Well described. Cochrane review says Arigorous in its methodology.

Methodological standards in primary studies: RCT where at least one group Rx'd antibiotics for AOM. NOT studies of bacterial pathogens; myringotomy; type of OM not clear; extraction of data for children (4/52 to 18 yrs) not possible; ROM; AOM failure management. Eligible studies weighted for quality.

Demographics of study populations: mainly white (75%) infants and preschoolers, mainly USA, Canada, UK.

Validity

Study type (meta analysis) is appropriate for the questions.

Tested for homogeneity.

Publication bias discussed and concluded as unlikely.

Results

For primary symptom control:
Any antibiotic relieved 14% more than no antibiotic. (13.7, 95% CI 8.2-19.2).

No advantage in broader spectrum antibiotics over simpler, cheaper drugs.

Therefore ARR = 14, NNT to relieve symptoms = 7.

Authors conclusions:

- Modest but significant efficacy antibiotics over placebo
- Amoxicillin & cotrimoxazole as effective as amox / clavanate, cephalosporins
- β-lactamase stable drugs of no advantage in efficacy, avoidance of mastoiditis and may increase bacterial drug resistance.
- Effectiveness of treatment in community may be lower than these studies as diagnostic certainty 58-73% only.
- Cannot detect the 1:7 that will benefit
- and cheaper
- efficacy studies based on 100% diagnostic certainty.

No difference between short course (<7/7) antibiotics or long course.
Concludes that decision whether or not antibiotic should be used rests as a negotiated decision with parents - their value judgement as to whether an NNT of 7 justifies the cost/risk. When an antibiotic is decided on, the safest/cheapest combination should be used.

Del Mar, Glasziou, Hayem: *Are antibiotics indicated as initial treatment for children with acute otitis media? A meta-analysis.*

Study type / grade

Meta-analysis. (Grade I evidence if the meta analysis asks the same questions as ours.)

• Only RCT of antibiotic vs placebo. (Therefore can potentially answer only the first of our questions).

• Studies were of empiric treatment (no bacterial identification made) of acute OM - (excluded ROM, OME, prophylaxis, etc).

• Strong methodology of selection of the primary studies.

Outcomes

Primary: clinical response to antibiotics

C pain at 24 hrs, 2-7 days.

Secondary: perforation, deafness at 1/12 and 3/12, contralateral AOM, ROM.

C vomiting, diarrhoea, rash.

Design

Focus on discrete clinical question? The absolute efficacy of antibiotics in AOM. (Our first question).

Explicit description of the literature search? Well described and thorough

Methodological standards in primary studies: RCT where at least one group Rx'd antibiotics for AOM. NOT studies of bacterial pathogens; myringotomy; type of OM not clear; extraction of data for children (4/52 to 18 yrs) not possible; ROM; AOM failure management. Eligible studies weighted for quality.

Demographics of study populations: mainly European, USA, Canada. 7/12 to 15 yr age range. No description of race. Described consistency with developed world study and increased risks / poor outcomes in Third World. (Very low incidence mastoiditis in developed world, a lot higher in Third World.

Validity Study type (meta analysis) is appropriate for the question.

Tested for homogeneity.

Publication bias not discussed but unlikely as results consistent and in same direction.

Results

Outcome	Control (%)	Treatment (%)	Rate Reduction (%)	NNT
Pain at 24 hours	39.6	39	0	infinite
Pain at 2-7 days	14.3	9.7	4.6	21*
Perforation	7.3	3.7	3.6	27**
Deafness 1 month	34	35	not significant	
Deafness 3 months	26	21	not significant	
Contralateral AOM	16.6	10.6	6	17
Recurrent OM	21.6	21.6	0	
Vomiting, Diarrhoea, Rash	10.7	16.5	-5.8	17

* Worked out another way - 14.3% of children had pain persisting 2-7 days, antibiotics reduced this pain in 41%, giving an NNT of 17.
** not statistically significant.

Authors conclusions: Open discussion with parents giving them the information on which to balance a value judgement of benefits vs risks and costs.

Process Plan

Definitions

Middle ear effusion (MEE):
Fluid in the middle ear regardless of cause; hearing loss +/-; diagnosis requires tympanometry or pneumatic otoscope.

Myringitis:
Erythema of the tympanic membrane without MEE.

Acute otitis media (AOM):
MEE with rapid onset symptoms.

Recurrent otitis media (ROM):
at least three episodes of AOM in past 6/12, or 4 in past 12/12.

Otitis Media with Effusion (OME):
MEE without signs or symptoms of AOM.

What are we trying to do?

- Define options for care.
- What choices are there, and what are the consequences of those choices?
- Define outcomes of interest.
- Severity and duration of pain.
- Deafness (rate of OME after AOM).
- Adverse effects.
- Recurrent attacks (ROM).
- Cost of care

Define the Evidence

- Quantify the levels of benefit, harm and cost.

Incorporate Values

- Outcomes of importance to parents.
- Outcomes of importance to health professionals (eg antibiotic resistance)

Who should be involved?

Who are the key stakeholders?

- Children represented by parents.
- GPs, Practice Nurses.
- Specialists - paediatricians, ? ENT surgeons.
- IPA - quality and budgetary considerations.

Processes

Problem Identification

This problem already identified as an important problem where there is a gap between current knowledge and current practice. It is very common so is of high volume even if relatively low cost.

Suitability Screen

First level Screen

we do have doctor/nurse time, analytic resources, implementation capacity and administration support to be able to do this.

Second level Screen:

Owner: S Foote

Can we measure proposed change. No readily available internal data at this stage but it is possible to collect some and repeat in the future to measure change.

Literature search: Shows that there is little evidence to support widespread use of antibiotics as an initial treatment for AOM; the NNT for better pain control at 2/7 varies between 7 and 17; there is no advantage in pain control at 24/24; that antibiotic resistance is growing; risks of vomiting, diarrhoea and rash double with antibiotics; reduced contralateral AOM but little difference in ROM or OME. Also widespread variation in practice.

Is the size and importance of the gap worth the effort. Probably yes but need internal data to be sure of that.

Can we implement the change. Yes, using written material for professionals and parents, cellgroups, academic detailing, feedback.

Internal Data

We do not need this data to prove or disprove issues related to outcomes of use or non use of antibiotics in AOM - the external evidence provides that proof. Therefore, the data we need is to monitor change or compliance with the guideline - ie have the efforts of developing and implementing the guideline resulted in a change of practice.

***Suggested data*:**

Outcome Category	Measurable Outcomes	Source of Data	Comments
Health status	Symptom control ROM OME Adverse effects	• Surveys • Ultimately from a collective clinical information system	Monitoring outcomes of value for research and/or confirming that our results consistent with external evidence. Not necessary for this exercise
Patient satisfaction	Access to care Understanding of issues Satisfaction with process of care	• Surveys • Sentinel groups	Need to discuss on 2/7/97 how to involve patient in this guideline development, implementation and evaluation
Provider satisfaction	Current practice attitudes	Survey	
Cost/utilisation	Consultation rates Antibiotic use or not Which antibiotics Dose/duration	• Surveys • Chart pulls • External data	Need: number of AOM; a/b on initial Rx; a/b @ 48/24; which a/b, dose, duration; total cost/pt.

External Data or Evidence

Three recent meta-analyses are presented.

Reassess suitability and prepare balance sheet.

References

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2. Myers MW. Jick H. *Hospitalization for serious blood and skin disorders following use of co-trimoxazole.* British Journal of Clinical Pharmacology. 43(4):446-8, 1997 Apr.
3. Jick H. Derby LE. *A large population-based follow-up study of trimethoprim - sulfa-methoxazole, trimethoprim, and cephalexin for uncommon serious drug toxicity.* Pharmacotherapy. 15(4):428-32, 1995 Jul-Aug.
4. Tilyard M, Dovey S, Walker S. *Otitis Media Treatment in NZ General Practice*. NZ Med J 1997; 110:143-5
5. Rosenfeld R, et al. An Evidence-based approach to treating otitis media. Paed Clinics North America. 43:6; December 1996
6. Del Mar C, Glasziou P, Hayem M. *Are antibiotics indicated as initial treatment for children with acute otitis media? A meta-analysis*. BMJ 1997;314:1526-9.
7. Rosenfeld R. What to expect from medical treatment of otitis media. Paed Infect Dis J, 1995;14:731-8