Overview

- Aetiology
- Politics
  - Black
  - Target
  - NICE
- Management

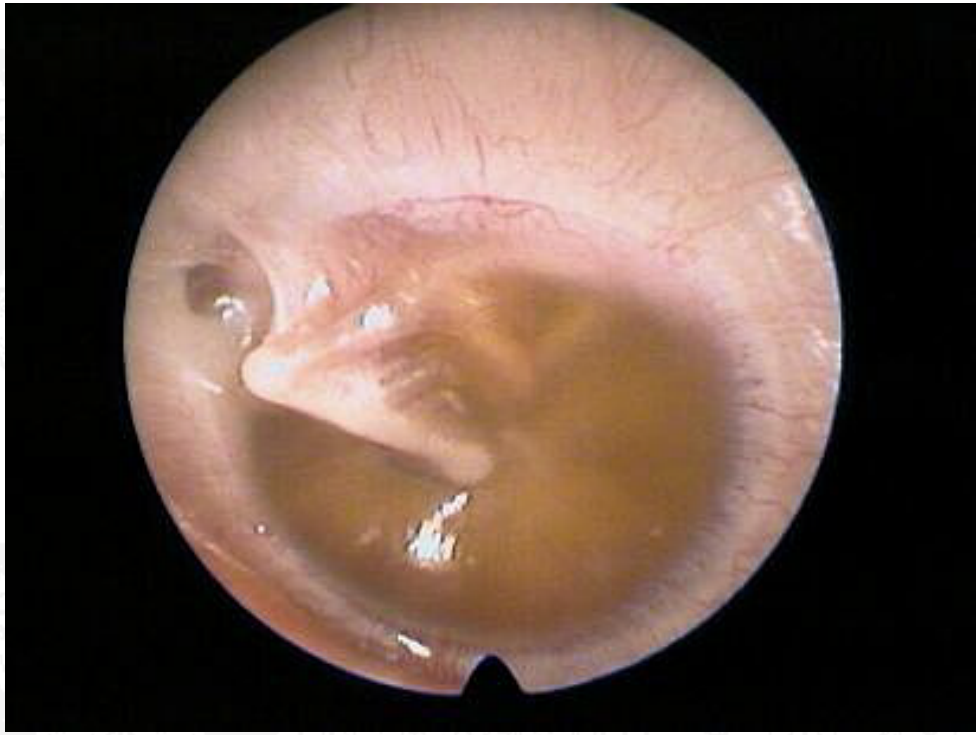
Glue Ear

1949 *R Jordan Laryngoscope 59: 1002-1015*

Mucoid otitis media
Catarrhal otitis media
Tubotympanitis
Otosalpingitis
Secretory otitis media
Non-suppurative otitis media
Mucotympanum
Serous otitis media

Jonathen Wathen , 1755, “mucus far up the Eustachian tube”

Otitis media with effusion (OME)



- Inflammation of the middle ear mucosa with accumulation of serous or mucoid fluid in the middle ear
- Usually self-limiting
- Concerns
  - Language development
  - Behaviour
  - Cognitive performance (into teenage years if late resolution)

? Precursor of significant morbidity

Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

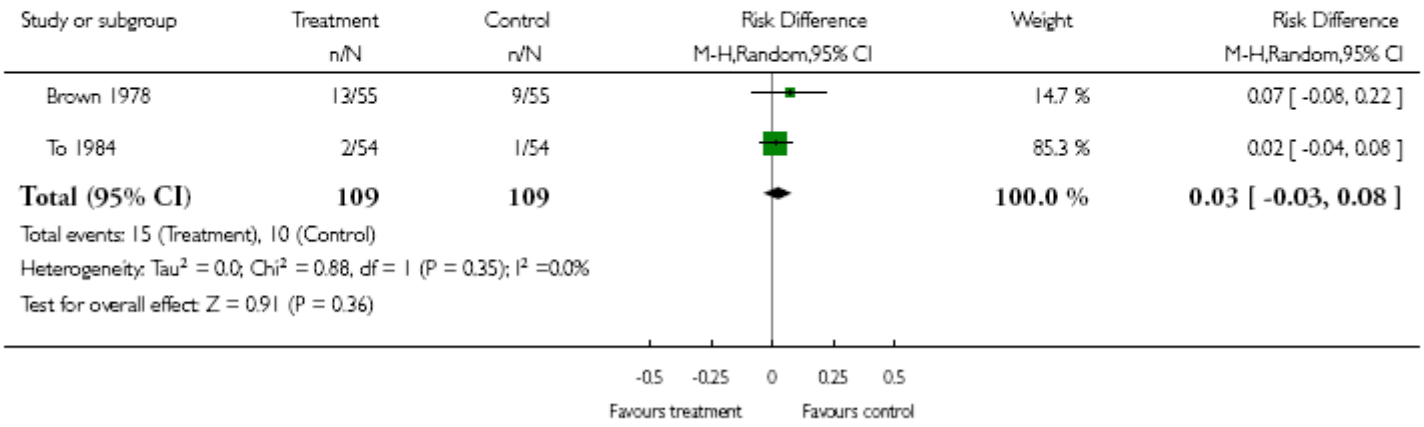
Lous J, Burton MJ, Felding J, Ovesen T, Rovers M, Williamson I

Analysis 10.2. Comparison 10 Adverse effects, Outcome 2 Retraction or atrophy (1 year).

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 10 Adverse effects

Outcome: 2 Retraction or atrophy (1 year)



Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

Lous J, Burton MJ, Felding J, Ovesen T, Rovers M, Williamson I

Analysis 10.5. Comparison 10 Adverse effects, Outcome 5 Tympanic membrane abnormalities, ears (3 to 4 years after initial grommet).

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 10 Adverse effects

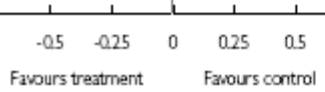
Outcome: 5 Tympanic membrane abnormalities, ears (3 to 4 years after initial grommet)

Study or subgroup	Early treatment n/N	Control(late treatm) n/N	Risk Difference M-H,Random,95% CI	Weight	Risk Difference M-H,Random,95% CI
Johnston 2004	185/294	93/268		100.0 %	0.28 [0.20, 0.36]
Total (95% CI)	**294**	**268**		**100.0 %**	**0.28 [0.20, 0.36]**

Total events: 185 (Early treatment), 93 (Control(late treatm))

Heterogeneity: not applicable

Test for overall effect: Z = 6.97 (P < 0.00001)

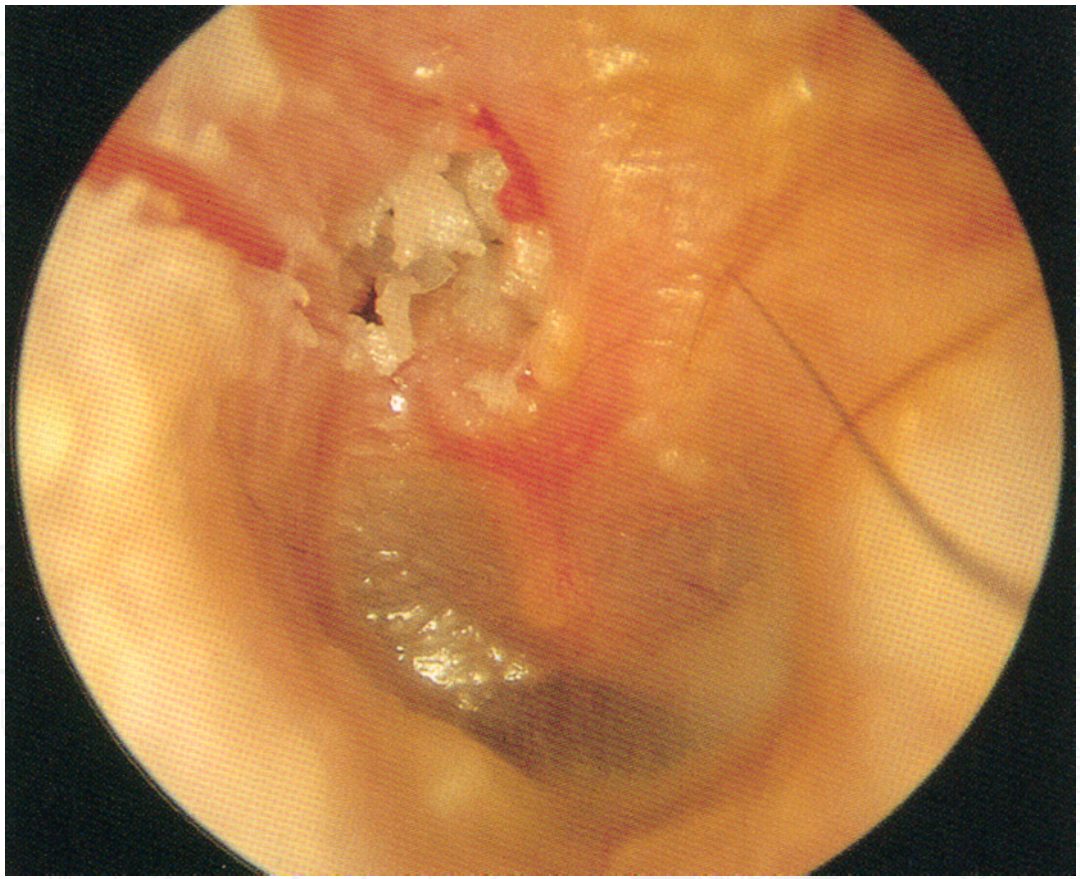


Sequelae post VT insertion

• Tympanosclerosis		40%
• Focal atrophy		18%
• Delayed otorrhoea		30-50%
• Early post-op otorrhoea		10-20%
• Recurrent otorrhoea		9%
• Chronic otorrhoea		4%
• TM perf	9% long term	1% short term
• Tube displacement middle ear		0.4%
• Acquired cholesteatoma		<0.2%

- Evidence Based Otitis Media, Rosenfeld, Bluestone, 1999

? Precursor of significant morbidity



Risk Factors

Host factors

- Age – bimodal (peaks aged 2 & 5)
- Sex M>F (1.2:1)
- Family History – Older sib
- Associated Conds.
  - Cleft Palate,
  - Down's,
  - Ciliary dyskinesia,
  - Craniofacial syndromes etc.

Environmental factors

- Season (winter >summer 2:1)
- Maternal Smoking
- Bottle feeding
- Day Care Centre

Risk Factors - Infection

- Acute otitis media
  - Respiratory / Bacterial infection stimulate release of inflammatory mediators with up-regulation of mucin gene and thereby effusion
  - Culture planktonic form = free culturable dividing cells
  - ? Significance of the “sterile” culture
    - PCR techniques demonstrate bacterial mRNA in culture –ve effusions
    - ME biopsy demonstrate “biofilm” colonies
      - Community of bacteria embedded in slime of extracellular polymeric substances (polysaccharides, nucleic acids & proteins) that adhere to an inert or living surface

Risk Factors
Amenable to drugs

Allergy

- Allergy incidence in OME 14% - 89 %

  15 -25 % if matched controls
- Cellular & Humoral mediators of allergic inflammation active in OME
- Eosinophilic degranulation, T cells, IL-4, IL-5 in atopic children with OME but not in non-atopics
- 25-30 % children with OME have allergy as a factor. Treatments may become more specific in future.

Reflux

- 83% effusions contained pepsin/pepsinogen concentrations 1000x>serum
  - Facilitates bacterial colonisation (planktonic/biofilm)

An Epidemic of Grommets

BRITISH MEDICAL JOURNAL VOLUME 290 29 JUNE 1985

For Debate . . .

Glue ear: the new dyslexia?

NICK BLACK

Abstract

Several factors have led to the current epidemic of surgery for glue ear in children, including the widespread introduction of audiometry; greater recognition of the presence of fluid in the middle ear by general practitioners; the availability of more otolaryngologists; and technical advances such as the availability of antibiotics to treat postoperative infections and of flanged tympanostomy tubes (grommets). The need of surgeons to fill the vacuum caused by the decline in the number of adenotonsillectomies, and the fact that a diagnosis of glue ear legitimises the continued use of these operations, may also have contributed to the increase. Finally, glue ear may provide parents with a medical explanation of their children's poor educational performance, as the term dyslexia did in the past. The high social and public costs of this operation demand a reappraisal of its increasing use.

The third epidemic of myringotomy

- Improved recognition
- Greater number of ENT surgeons
- Flanged tympanostomy tubes
- Provision of a medical explanation of child's poor performance

Filling the tonsillectomy void

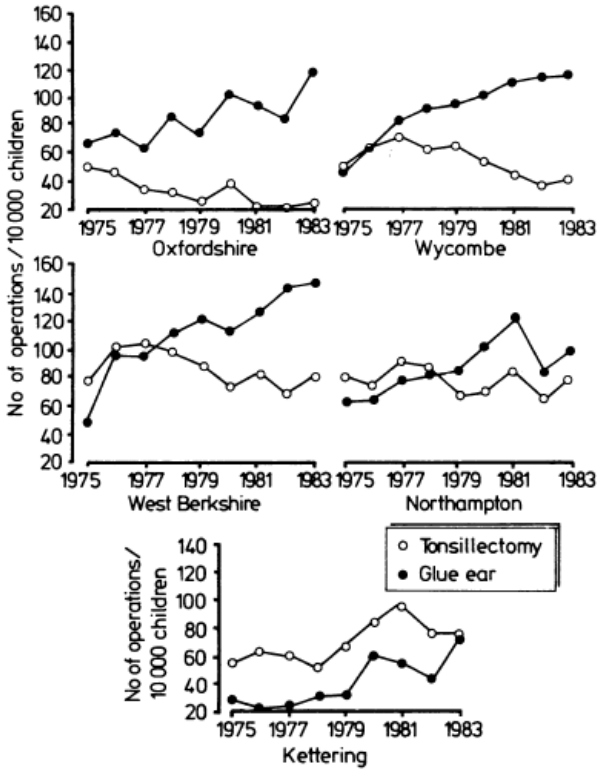


FIG 2—Secular trends in rates of surgery for glue ear and tonsillectomy/10 000 children aged 0-9 in five health districts in Oxford Regional Health Authority 1975-83.

- Higher rate of surgery SC I vs SC V
- Rise in rate of surgery yet no increase in prevalence
- Oxford 79.9/10,000
- Cheltenham 23.7/10,000

Effective HEALTH CARE

The Treatment of Persistent Glue Ear in Children

Are surgical interventions effective in combating disability from glue ear?

- Glue ear is the most common cause of hearing impairment and reason for elective surgery in children. There are doubts whether current high levels of surgery are necessary.
- The average annual rate of surgical treatment for glue ear in England is about 5/1000 children under the age of 15. There is a large regional variation in rates of surgical treatment for glue ear.
- Most episodes of glue ear are of short duration and spontaneously resolve. There is insufficient evidence to demonstrate a causal link between glue ear and significant disability.
- Grommets and adenoidectomy, alone or in combination, are equally effective and reduce mean hearing impairment by less than 12 decibels. There is a large variation in the effect between children. The clinical significance of small improvements is uncertain.
- Myringotomy alone, and tonsillectomy alone or in combination, are ineffective interventions.
- Introducing a period of *watchful waiting* is likely to decrease surgical activity for glue ear, with potential savings but improved access to quality audiology may increase resource use.
- Purchasers should develop protocols in conjunction with relevant professionals which should include direct access to audiological services for general practitioners, and the use of a *provisional waiting list* during a period of *watchful waiting*.
- Large multi-centre trials examining the effectiveness of a range of interventions using broader outcome measures are required.

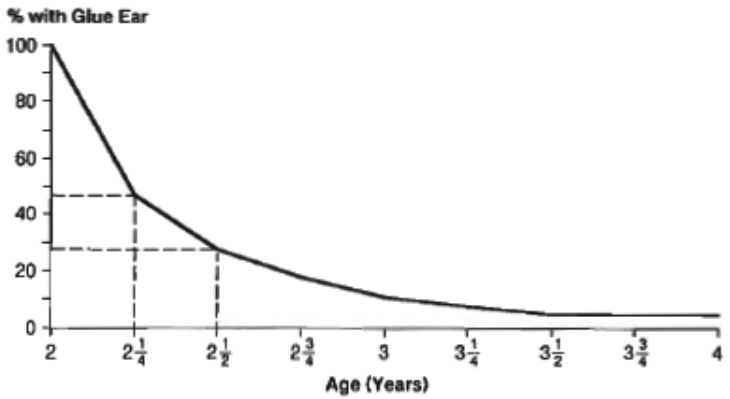
November 1992 Number 4

A BULLETIN ON THE EFFECTIVENESS OF HEALTH SERVICE INTERVENTIONS FOR DECISION-MAKERS

School of Public Health, University of Leeds; Centre for Health Economics, University of York; Research Unit, Royal College of Physicians.

It is funded by the Department of Health. The views expressed are those of the authors and not necessarily those of the DH.

Figure 2 *Spontaneous resolution of glue ear in a cohort of two-year olds.*



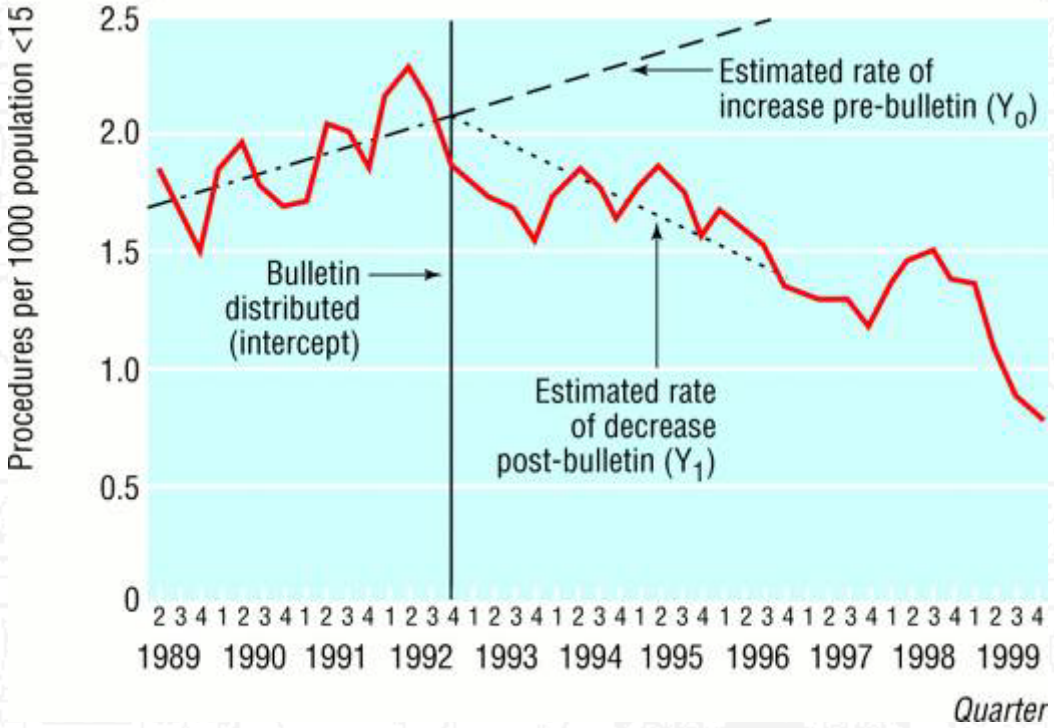
Source: Zielhuis[9].

- Purchasers & providers should scrutinise local practice and develop Protocols with ENT surgeons, GPs' SCMOs, community paediatricians & other relevant health professionals
- Recommend multicentre trial

Post E.H.C.B, 1992

Generalised linear model

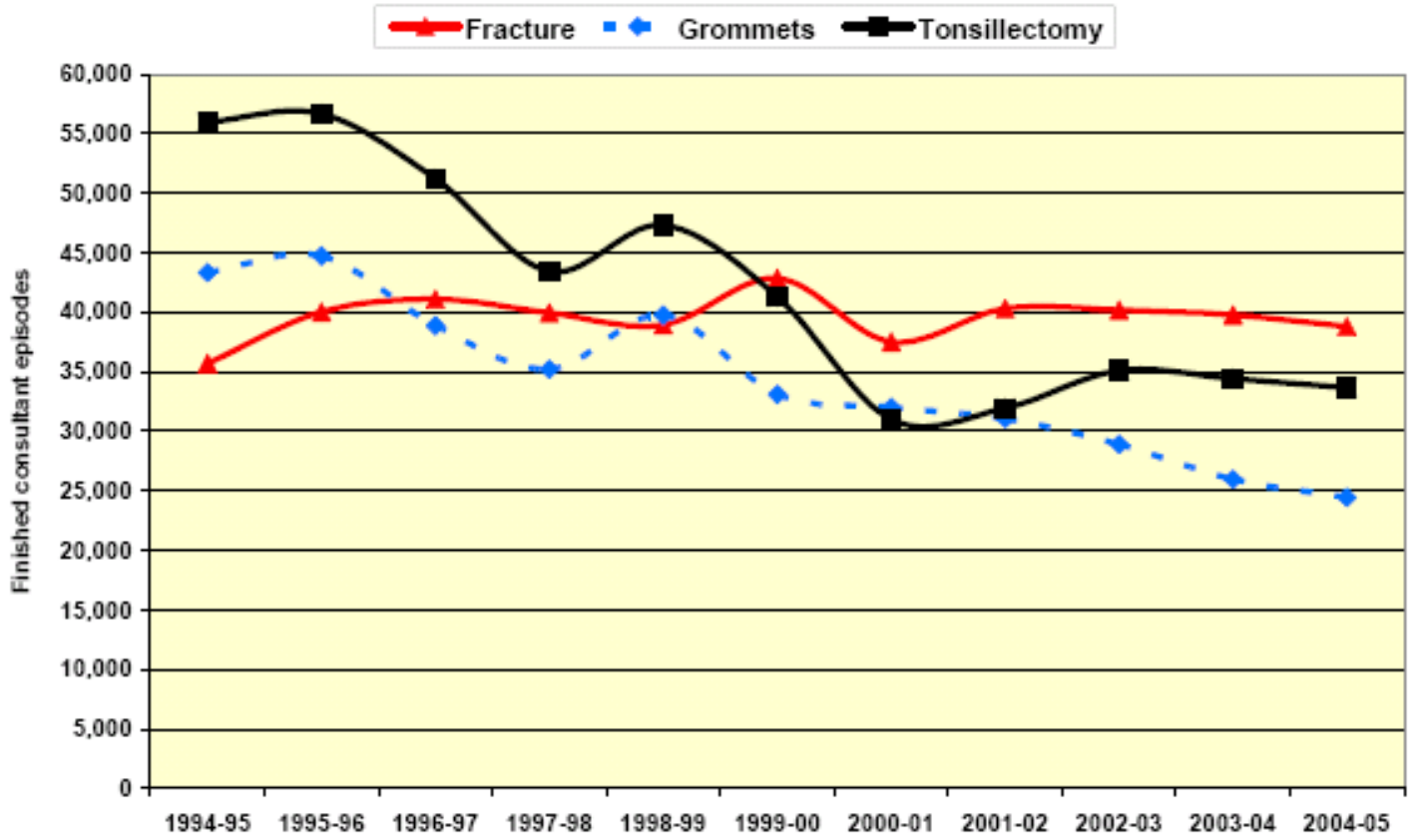
Effect	Bulletin	Estimate	Error	df	95% CI
Intercept		2.095	0.0830	13	1.915 to 2.274
Y_0	No	0.0257	0.0242	376	-0.0219 to 0.0732
Y_1	Yes	-0.0438	0.0169	376	-0.0770 to -0.0106



Mason, J. et al. BMJ 2001;323:1096-1097

BMJ

Trends in Children's Surgery 1994-2005: Evidence From Hospital Episode Statistics Data



DH Department of Health

TARGET

Trial of Alternative Regimens of Glue Ear Treatment

- Multicentre Trial 1994-1997
  - Inclusion Aged 3.5-7
    - No previous ear or adenoid surgery
    - Having B+B or B +C2 tympanograms
    - Bilat av. hearing threshold >20db + AC/BC gap >10dB
  - Exclusion
    - Severe general disease/ craniofacial abnormalities/ SN loss? Parents with language or literacy problems. If consultant felt it unethical to include in the study

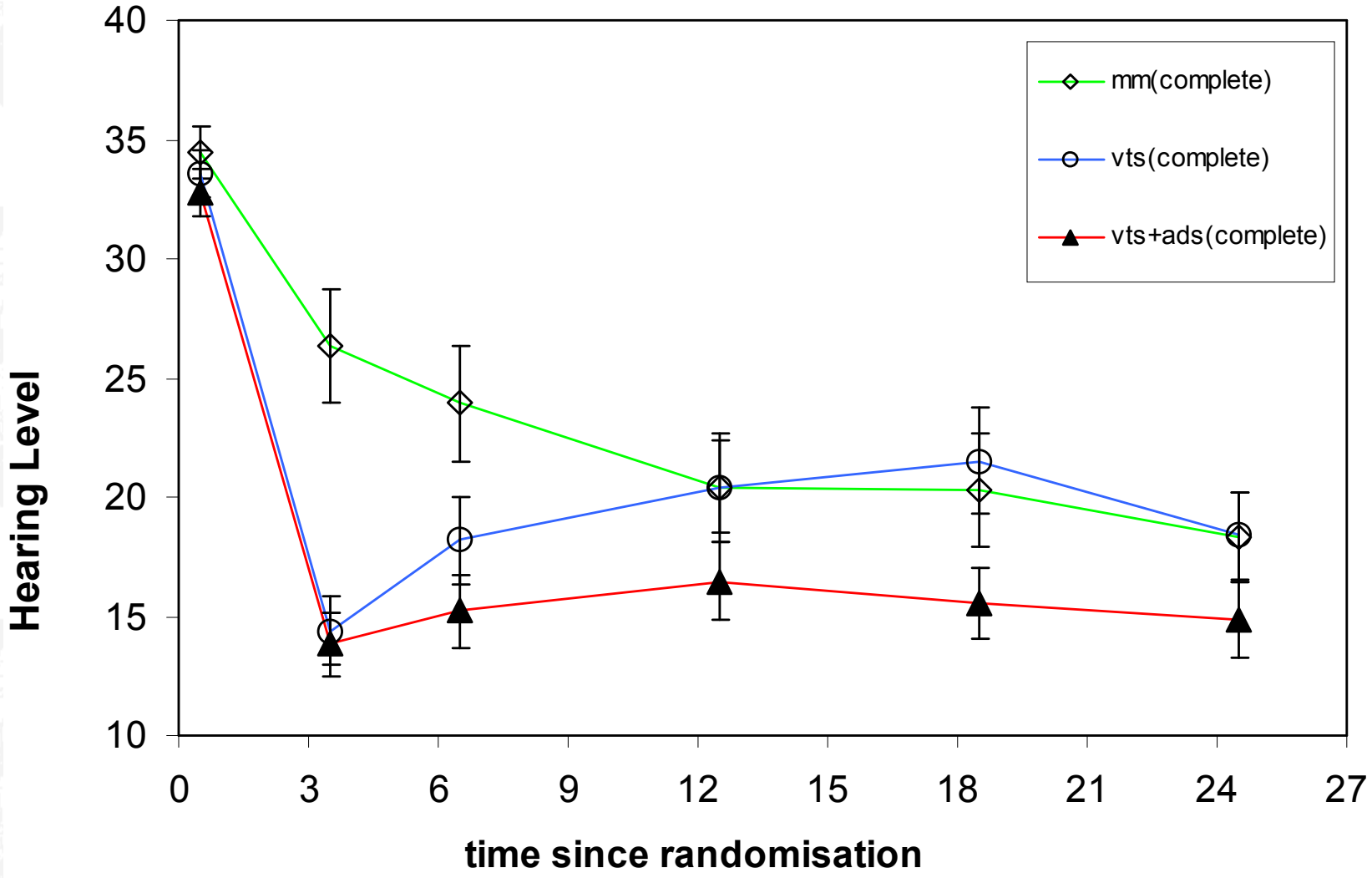
TARGET

Trial of Alternative Regimens of Glue Ear Treatment

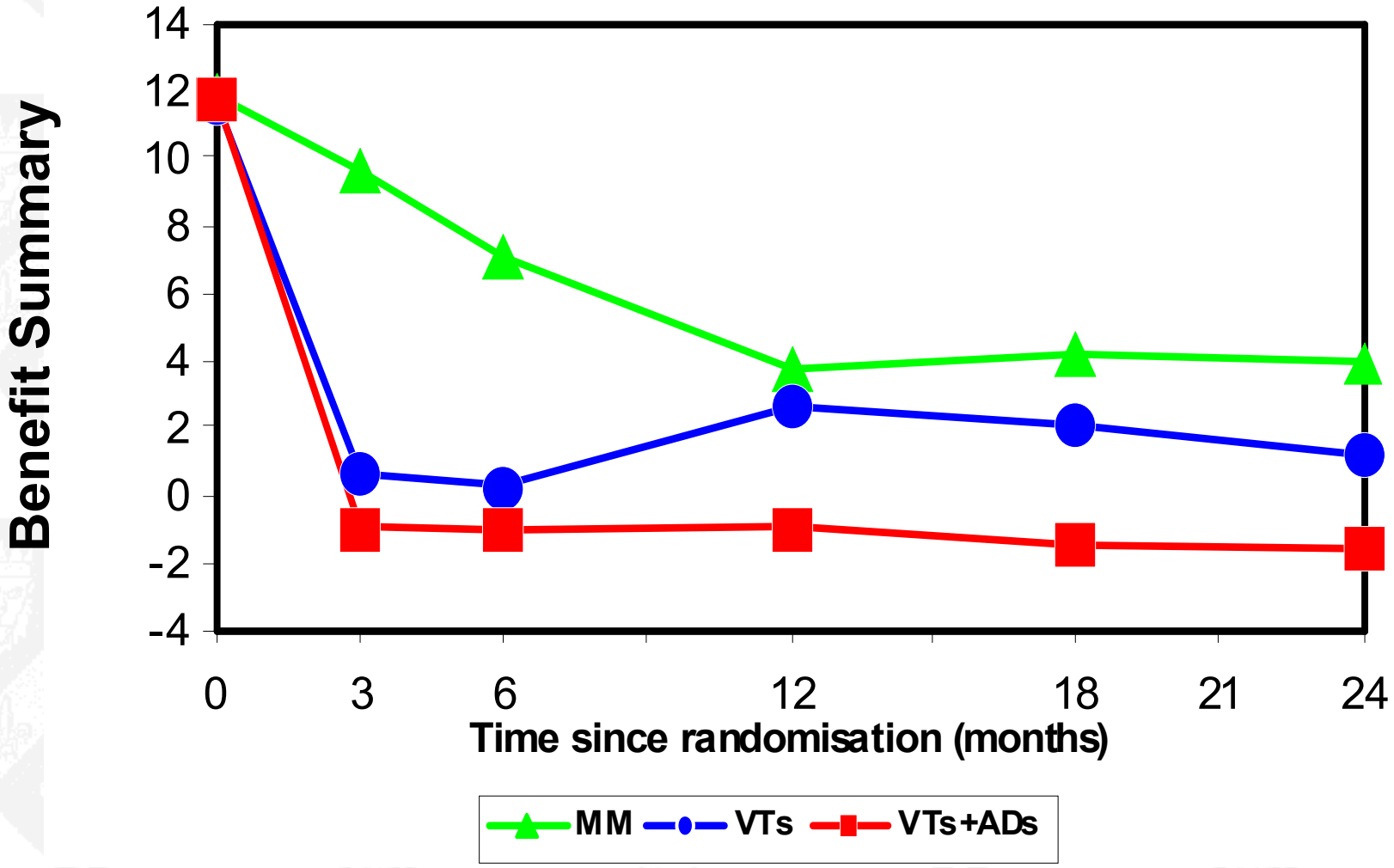
- 3831 screened tymps and audio
- 506 eligible for randomisation mm/vts/vts & as
- 376 randomised

TIME COURSE OF HEARING LEVEL

Maximum vs complete Hearing Level data



TIME COURSE OF "BENEFIT SUMMARY"
(EXCLUDING HL)



CONCLUSIONS

- For children over 3 yrs, short-stay VTs are indicated given a 20 dB HL over 3 months

  the 1-year treatment effect size is large for HL (» 1.2 SD)

- Combined VTs + ADs has benefit of an immediate effect (VTs) *plus* prolongation (ADs)

- Hearing level is a good surrogate predictor of the broader outcomes

18 weeks commissioning pathways

Glue ear in children

Supplementary information to be read in conjunction with the pathway

3.4 Definitive Treatments (Tx)	3.4.1 Consider group sessions for parents run by SLT/T-O-D or specialist ENT nurse with expert parent to ensure understanding & assist mitigation of impact. 3.4.2 Temporising treatments may alleviate symptoms 3.4.3 Wax clearance as tier 1or by irrigation/aural toileting by trained personnel with endoscope or microscope if medical tx failed. Consider hearing aids (postaural or bone conduction) hearing aid efficacy. Query soundfield amplification in school/nursery & attempt policy on this with Local Education Authority 3.4.4 Where there is specific underlying pathology then topical nasal steroids or cromoglycate treatment (age- dependent protocols), allergen avoidance, desensitisation. Evidence emerging. Specific treatment/management of other conditions 3.4.5 POA begins at the point of listing children for surgery & specific to this condition consider parental choice, previous surgery, complications, duration, hearing level, impact on life, comorbidity. Additionally pre-op tympanometry should confirm condition may have resolved in the time elapsed 3.4.6 Direct access to surgical list if sufficiently trained referring professional or agreement for physician, paediatrician. Essential to undertake preop tympanometry. Ventilation tubes ("grommets") offer short-term benefit to hearing while patent & in place (6-9 mnths) Adenoidectomy gives more persistent benefit to hearing & hence reduction in future surgery. It confers extra benefit for frequent URTI & is generally advised for those who have already had ventilation tubes once, upper airway obstruction or rhinosinusitis. Caution required in syndromic or comorbid children, balancing outcome against complications of surgery & anaesthesia including velopharyngeal insufficiency (transient <2%). Where new surgical techniques are used for adenoidectomy, comprehensive audit of bleed rate is necessary

Grommets in otitis media with effusion: an individual patient data meta-analysis

M M Rovers, N Black, G G Browning, R Maw, G A Zielhuis and M P Haggard

Arch. Dis. Child. 2005;90;480-485
doi:10.1136/adc.2004.059444

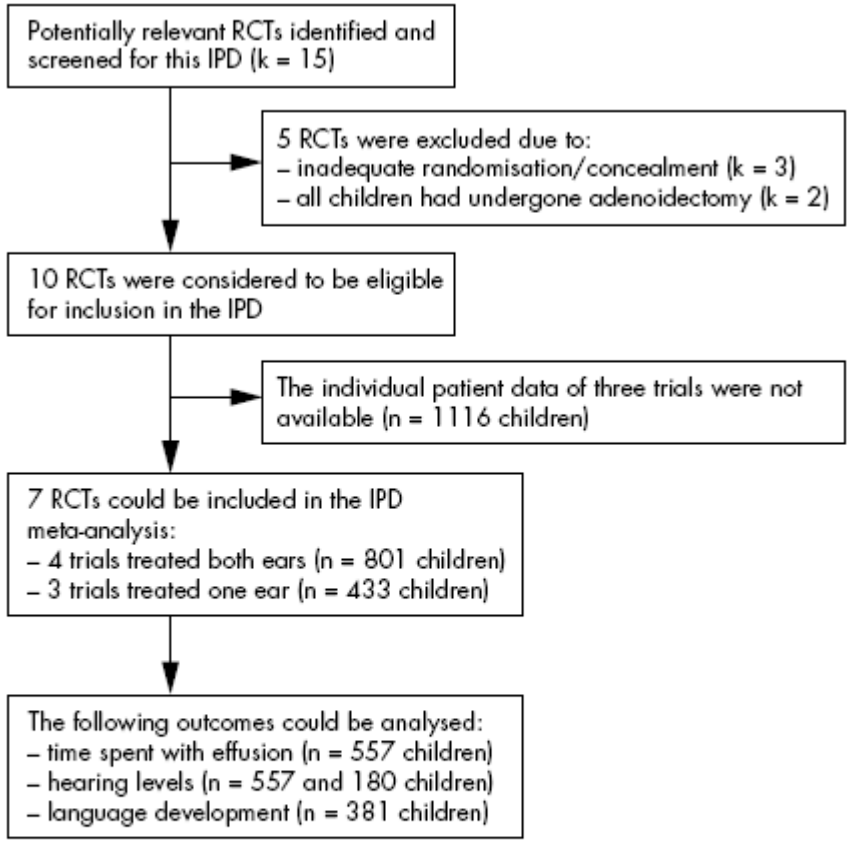


Figure 1 QUOROM flow chart.

Ventilation tubes might be used in young children that grow up in an environment with a high infection load (for example, children attending day-care)
or
in older children with a hearing level of 25 dB HL or greater in both ears persisting for at least 12 weeks.

Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

Lous J, Burton MJ, Felding J, Ovesen T, Rovers M, Williamson I

Findings

- the beneficial effect of grommets on hearing diminished during the first year.
- most grommets come out over the first year.
- No evidence that grommets help speech and language development.

Recommendation

- Watchful waiting would appear to be an appropriate management strategy for most children with glue ear

THE COCHRANE COLLABORATION®

- January 2005 / January2009

BMJ

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith and Jill P Pell

BMJ 2003;327;1459-1461
doi:10.1136/bmj.327.7429.1459

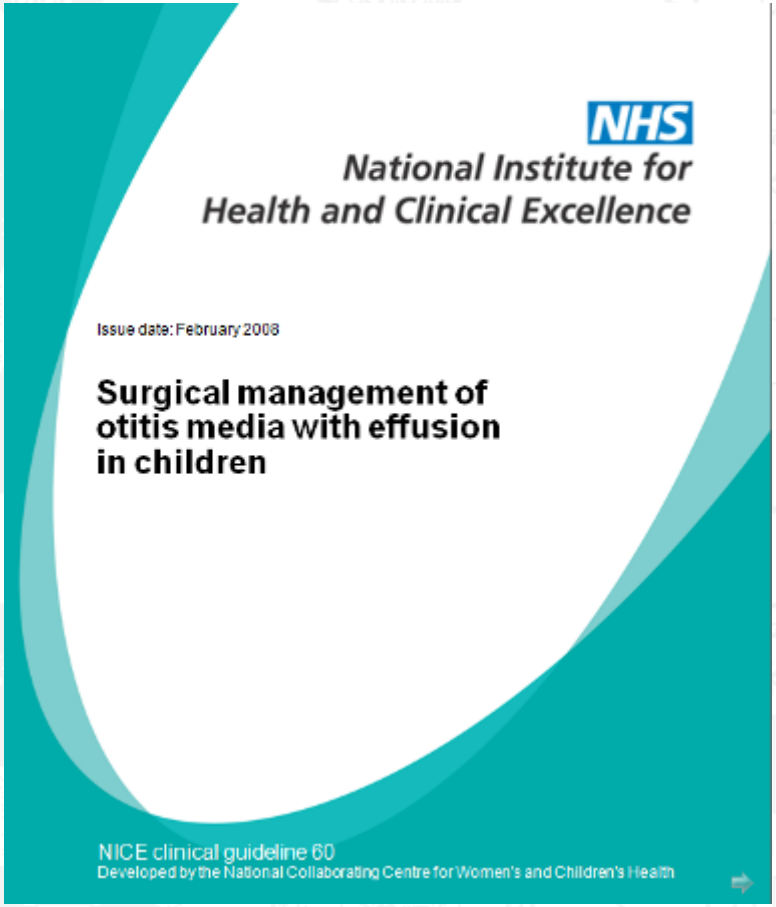
RCTs

No RCTs of parachute intervention

Conclusions

"Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational studies…..everyone might benefit if the most radical protagonists of EBM organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute"

“Balanced Multidisciplinary View”



- Peter Bull
- Kenneth Pearman
- Patrick Sheehan
- Mark Haggard
- Ewa Raglan

Assessment of child with suspected OME

History

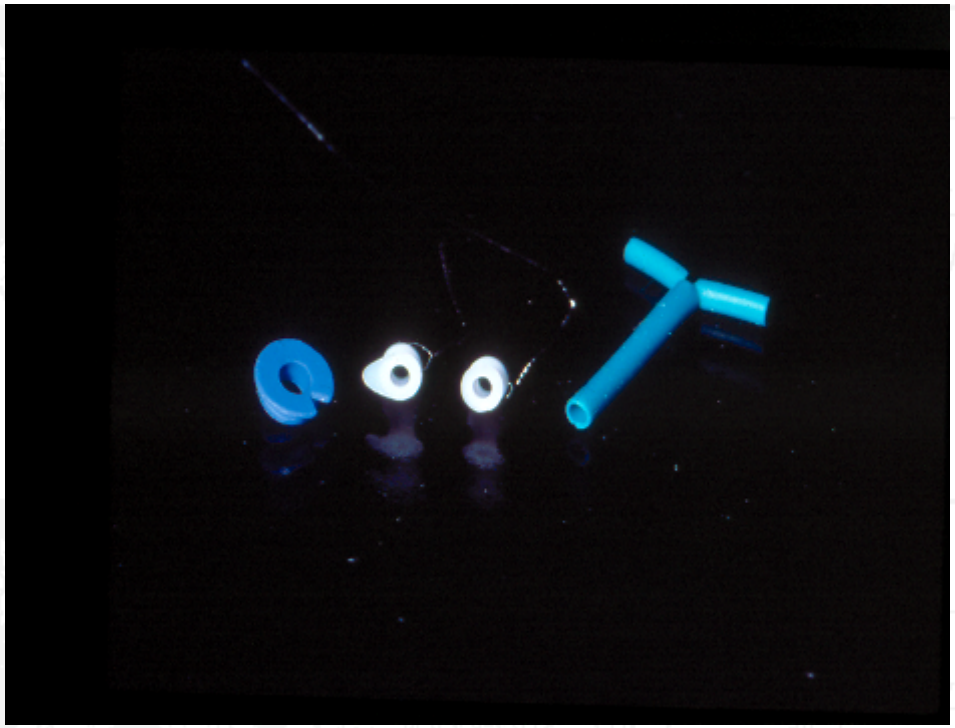
- poor listening skills
- indistinct speech or delayed language development
- inattention and behaviour problems
- hearing fluctuation
- recurrent ear infections or upper respiratory tract infections
- balance problems and clumsiness
- poor educational progress

Clinical examination

- otoscopy
- general upper respiratory health
- general developmental status

Investigation

- hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
- tympanometry.



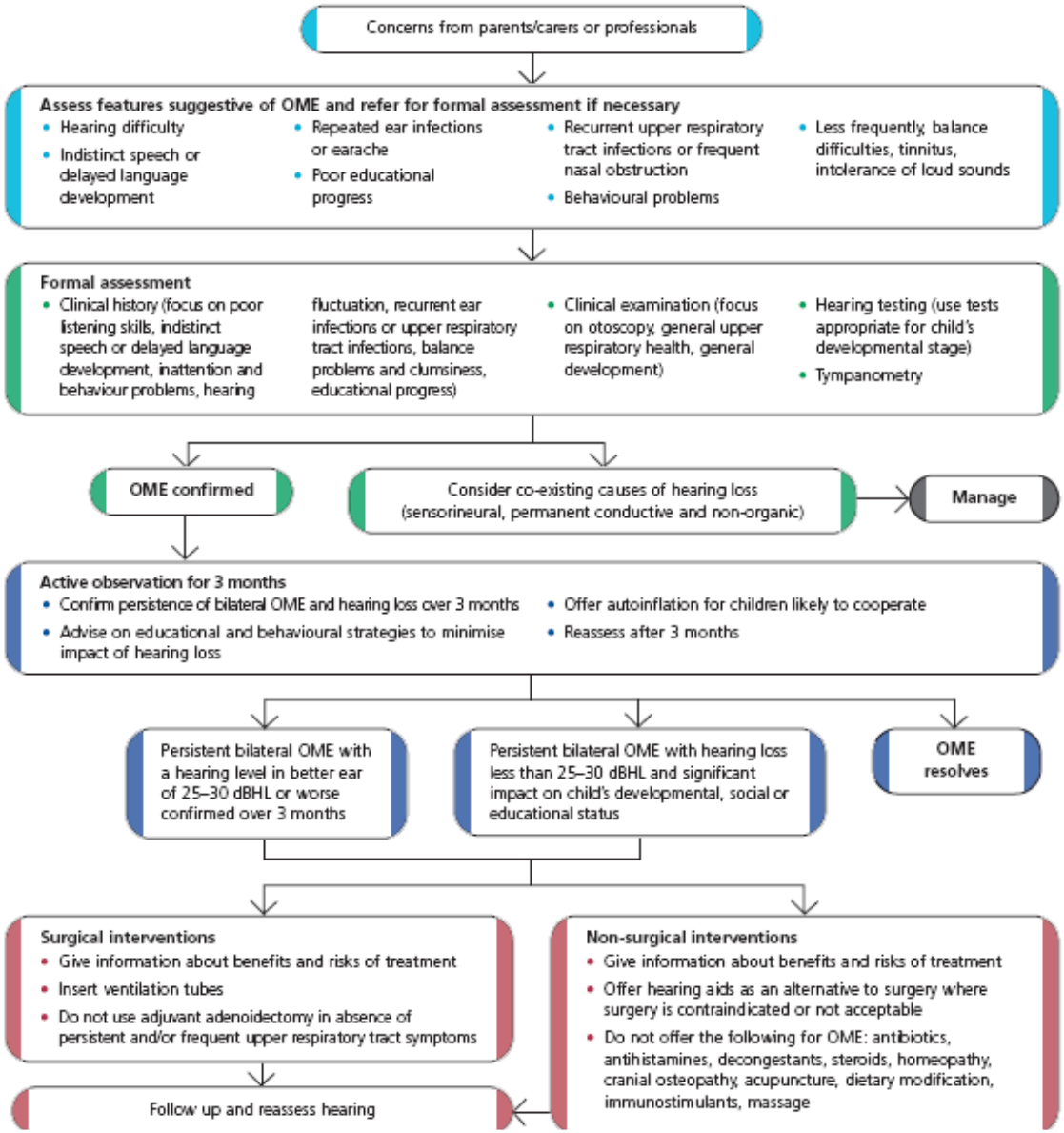
Children who will benefit from surgical intervention

Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.

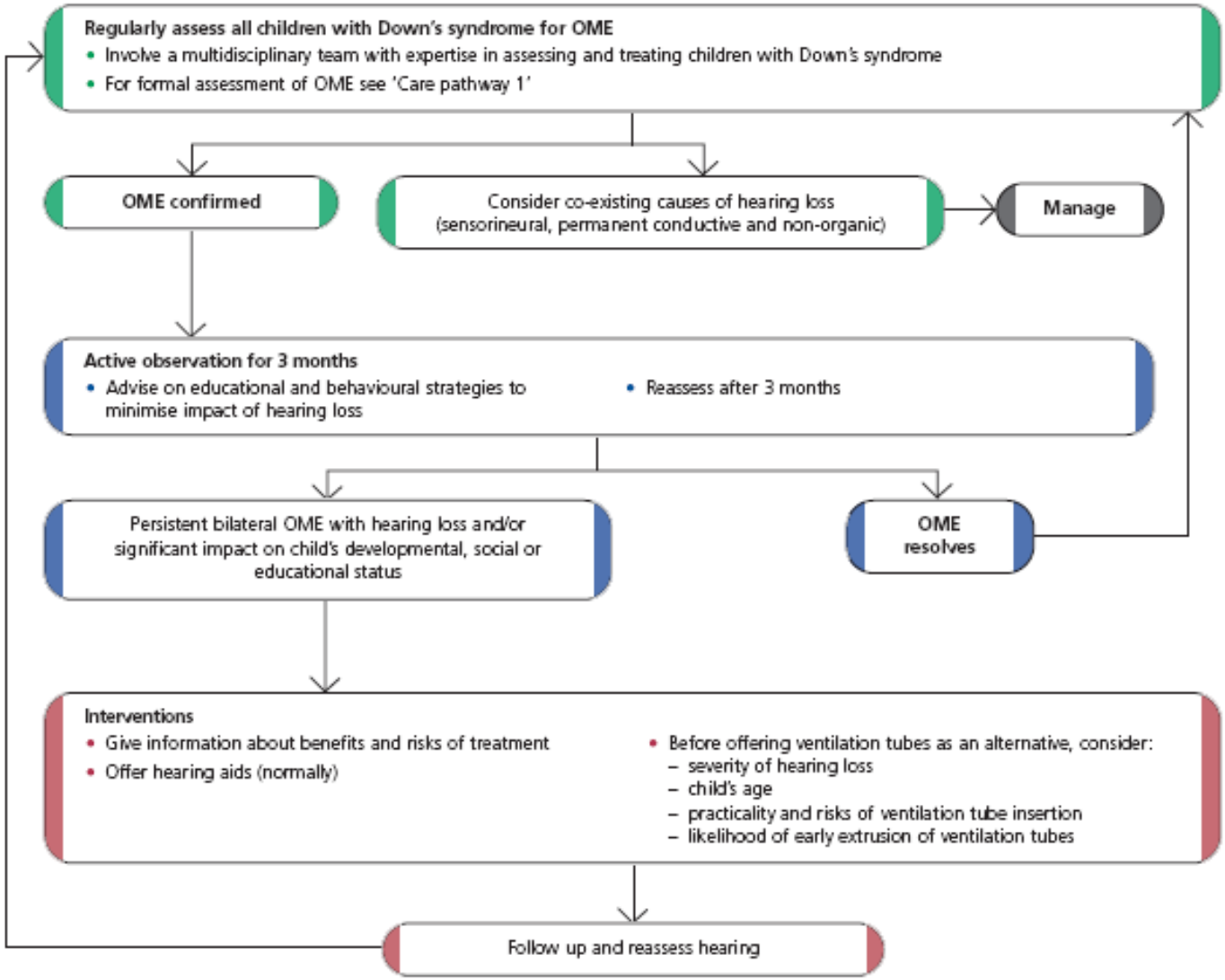
The following treatments are not recommended for the management of OME:

- antibiotics
- topical or systemic antihistamines
- topical or systemic decongestants
- topical or systemic steroids
- homeopathy
- cranial osteopathy
- acupuncture
- dietary modification, including probiotics
- immunostimulants
- massage.

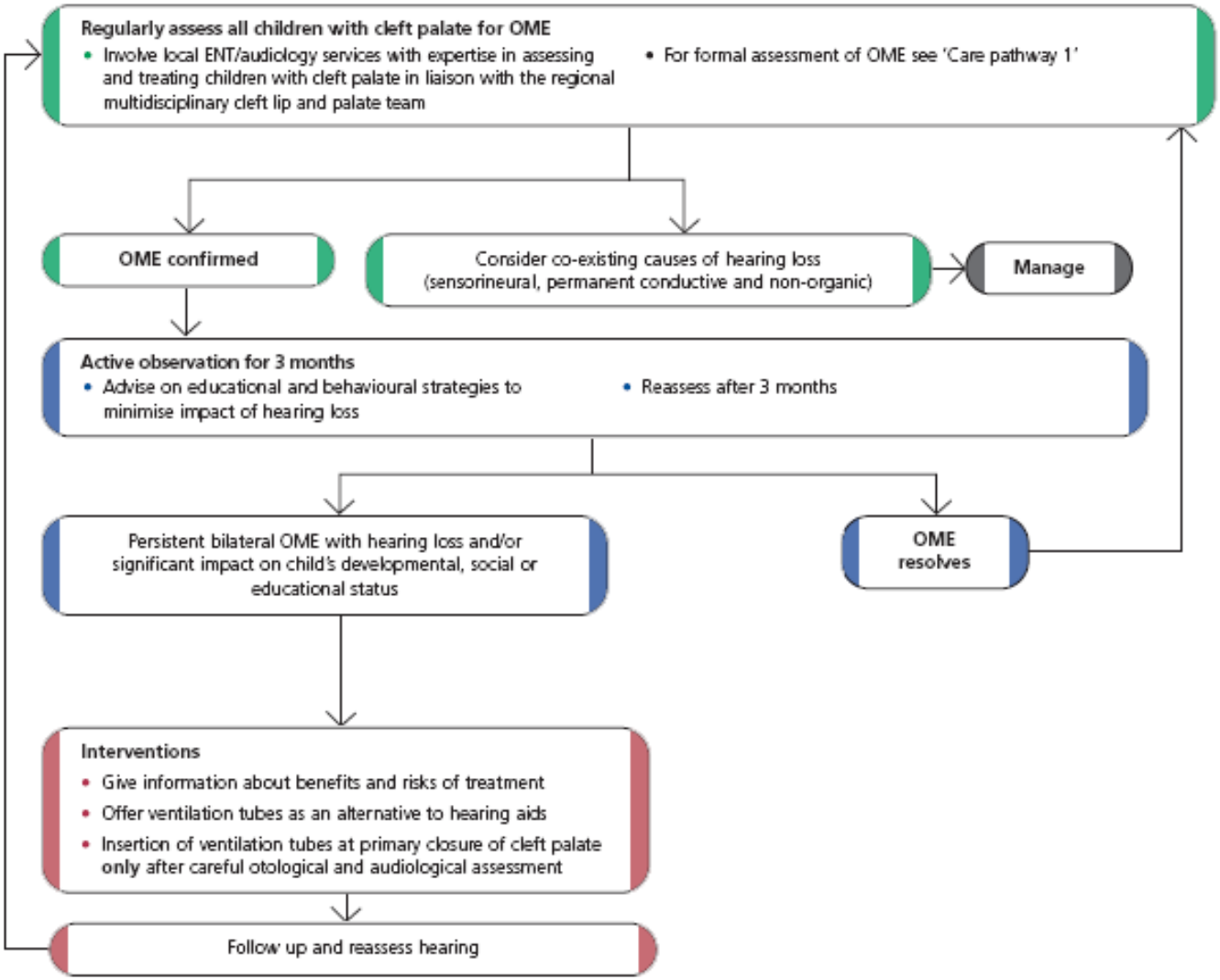
OME


Concerns from parents/carers or professionals
Assess features suggestive of OME and refer for formal assessment if necessary
Hearing difficulty
Indistinct speech or delayed language development
Repeated ear infections or earache
Poor educational progress
Recurrent upper respiratory tract infections or frequent nasal obstruction
Behavioural problems
Less frequently, balance difficulties, tinnitus, intolerance of loud sounds
Formal assessment
Clinical history (focus on poor listening skills, indistinct speech or delayed language development, inattention and behaviour problems, hearing fluctuation, recurrent ear infections or upper respiratory tract infections, balance problems and clumsiness, educational progress)
Clinical examination (focus on otoscopy, general upper respiratory health, general development)
Hearing testing (use tests appropriate for child's developmental stage)
Tympanometry
OME confirmed
Consider co-existing causes of hearing loss (sensorineural, permanent conductive and non-organic)
Manage
Active observation for 3 months
Confirm persistence of bilateral OME and hearing loss over 3 months
Advise on educational and behavioural strategies to minimise impact of hearing loss
Offer autoinflation for children likely to cooperate
Reassess after 3 months
Persistent bilateral OME with a hearing level in better ear of 25–30 dBHL or worse confirmed over 3 months
Persistent bilateral OME with hearing loss less than 25–30 dBHL and significant impact on child's developmental, social or educational status
OME resolves
Surgical interventions
Give information about benefits and risks of treatment
Insert ventilation tubes
Do not use adjuvant adenoidectomy in absence of persistent and/or frequent upper respiratory tract symptoms
Follow up and reassess hearing
Non-surgical interventions
Give information about benefits and risks of treatment
Offer hearing aids as an alternative to surgery where surgery is contraindicated or not acceptable
Do not offer the following for OME: antibiotics, antihistamines, decongestants, steroids, homeopathy, cranial osteopathy, acupuncture, dietary modification, immunostimulants, massage

Down's Syndrome



Cleft Palate

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Thank you

18 Week Commissioning Pathway - Glue Ear in Children 2008

Department of Health