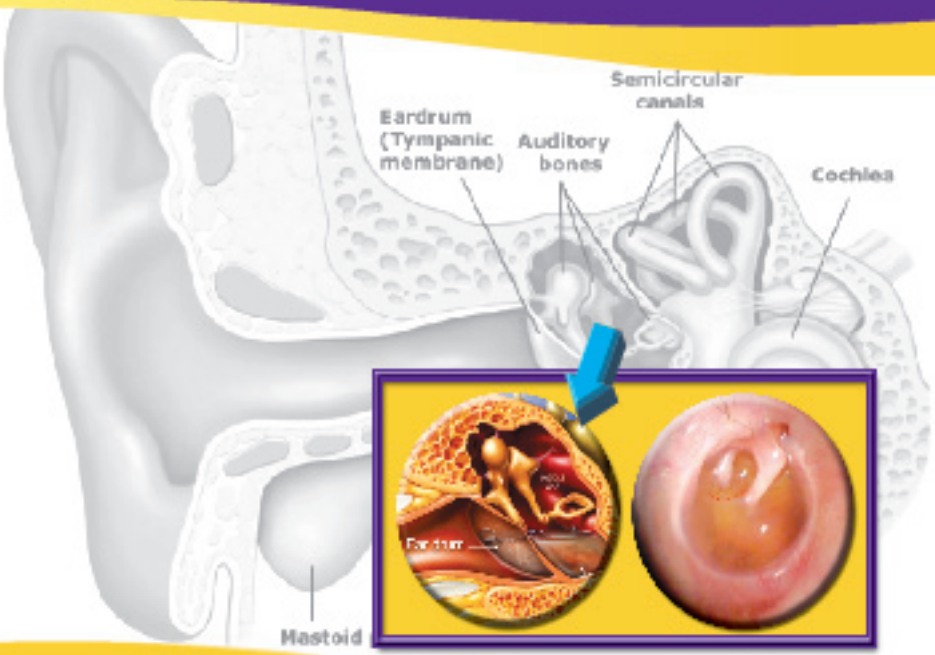
CLINICAL PRACTICE GUIDELINES

MOH/P/PAK/239.12 (GU)
July 2012

Management of Otitis Media with Effusion in Children



Ministry of Health Malaysia

Malaysian Society of Otorhinolaryngologists Head & Neck Surgeons (MSOHNS)

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STATEMENT OF INTENT

These clinical practice guidelines (CPG) are meant to be guides for clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not necessarily guarantee the best outcome in every case. Every healthcare provider is responsible for the management of his/her unique patient based on the clinical picture presented by the patient and the management options available locally.

These guidelines were issued in 2012 and will be reviewed in 2016 or sooner if new evidence becomes available.

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LEVEL OF EVIDENCE

Level	Study design
I	Evidence from at least one properly randomised controlled trial
II -1	Evidence obtained from well-designed controlled trials without randomisation
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or group
II-3	Evidence from multiple time series with or without intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III	Opinions of respected authorities based on clinical experience; descriptive studies and case reports; or reports of expert committees

SOURCE: US / CANADIAN PREVENTIVE SERVICES TASK FORCE 2001

GRADES OF RECOMMENDATION

A	At least one meta analysis, systematic review, or RCT, or evidence rated as good and directly applicable to the target population
B	Evidence from well conducted clinical trials, directly applicable to the target population, and demonstrating overall consistency of results; or evidence extrapolated from meta analysis, systematic review, or RCT
C	Evidence from expert committee reports, or opinions and /or clinical experiences of respected authorities; indicates absence of directly applicable clinical studies of good quality

SOURCE: MODIFIED FROM THE SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK (SIGN)

Note: The grades 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.

GUIDELINES DEVELOPMENT AND OBJECTIVES

GUIDELINES DEVELOPMENT

The development group for this Clinical Practice Guidelines (CPG) is from the Ministry of Health (MoH), Ministry of Higher Education and private sector. The group consists of otorhinolaryngologists, paediatrician, family medicine specialists, public health physicians, audiologists, a pharmacist and an assistant medical officer. There was active involvement of the multidisciplinary Review Committee (RC) during the process of development of these guidelines.

Literature search was carried out at the following electronic databases: Guidelines International Network (G-I-N), Pubmed/Medline, Cochrane Database of Systemic Reviews (CDSR), Database of Abstracts of Reviews of Effectiveness (DARE), Journal full text via OVID search engine, International Health Technology Assessment websites (refer to **Appendix 1** for Search Terms). In addition, the reference lists of all retrieved articles were searched to identify relevant studies. Experts in the field were also contacted to identify further studies. All searches were officially conducted between 17 August 2010 and 11 August 2011. Literature searches were repeated for all clinical questions at the end of the CPG development process allowing any relevant papers published up until 21 February 2012 to be considered. Future CPG updates will consider evidence published after this cut-off date. The details of the search strategy can be obtained upon request from the CPG secretariat. Search was limited to literature published in English.

Reference was also made to other guidelines on Otitis Media with Effusion such as National Collaborating Centre for Women's and Children's Health – Surgical Management of Children with Otitis Media with Effusion (OME) (2008); American Academy of Pediatrics - Clinical Practice Guideline, Otitis Media with Effusion. Pediatrics (2004); American Academy of Family Physicians (AAFP), American Academy of Otorhinolaryngology-Head And Neck Surgery (AAO-HNS), Academy of Pediatrics (AAP) Subcommittee on Otitis Media with Effusion - Clinical Practice Guideline, Otitis Media with Effusion (2004); Scottish Intercollegiate Guidelines Network - Diagnosis and Management of Childhood Otitis Media in Primary Care (2003); National Institute for Clinical Excellence - Referral Advice, Persistent Otitis Media With Effusion (Glue Ear) In Children (2001). These CPGs were evaluated using the Appraisal of Guidelines for Research and Evaluation (AGREE) prior being used as references.

Fifteen clinical questions were developed under four sections and members of the development group were assigned individual questions within these subtopics (refer to **Appendix 2** for Clinical Questions).

The group members met a total of 20 times throughout the development of these guidelines. All literature retrieved was appraised using Critical Appraisal Skills Programme (Oxford) by at least two members and presented in the form of evidence tables and discussed during development group meetings. All statements and recommendations formulated then were agreed upon by both the development group and RC. Where evidence was insufficient, the recommendations were made by consensus of the development group and RC. These CPG are based largely on the findings of systematic reviews, meta-analyses and clinical trials, with local practices taken into consideration.

The articles used in theses guidelines were graded using the US/ Canadian Preventive Services Task Force Level of Evidence (2001), while the grading of recommendation was modified from grades of recommendation of the Scottish Intercollegiate Guidelines Network (SIGN).

On completion, the draft guidelines was sent for review by external reviewers. It was posted on the MoH Malaysia official website for comment and feedback from any interested parties. These guidelines had also been presented to the Technical Advisory Committee for CPG, and the HTA and CPG Council, MoH Malaysia for review and approval.

OBJECTIVES

GENERAL OBJECTIVE

- To provide an evidence-based guidance in the management of otitis media with effusion (OME) in children

SPECIFIC OBJECTIVES

- To provide evidence-based guidance for early detection and referral in preventing subsequent complication of OME at all levels of healthcare
- To provide evidence-based guidance in selecting the appropriate diagnostic tool
- To provide evidence-based guidance in selecting treatment options, plan and preventive measures available in the treatment of OME

CLINICAL QUESTIONS

Refer to **Appendix 2**

TARGET POPULATION

Children with OME (12 years old and below)

Special consideration:

Children with Down syndrome and cleft palate

TARGET GROUP/USER

This document is intended to guide healthcare professionals at all level of health care system including:

- Medical officers
- General practitioners
- Family Medicine Specialists
- Paediatricians
- Otorhinolaryngologists
- Audiologists
- Plastic surgeons
- Dental officers
- Allied health professionals
- Pharmacists
- Programme managers
- Other healthcare providers involved in managing patients with OME
- Healthcare provider trainees and medical students
- Professional societies

HEALTHCARE SETTINGS

Outpatient, inpatient and community setting

GUIDELINES DEVELOPMENT GROUP

Chairperson

Dr. Zulkiflee Salahuddin
Head of Department & Consultant Otorhinolaryngologist (Otology)
Hospital Raja Perempuan Zainab II
Kota Bharu, Kelantan

Members (alphabetical order)

Professor Dr. Asma Abdullah
Clinical Professor &
Consultant Otorhinolaryngologist
Faculty of Medicine, Pusat Perubatan
Universiti Kebangsaan Malaysia
Kuala Lumpur

Dr. Hafeza Ahmad
Otorhinolaryngologist
Hospital Putrajaya, Putrajaya

Ms. Jaclyn Teoh Pei Lee
Pharmacist
Bandar Puchong Jaya, Selangor

Mdm. Juliana Samsudin
Audiologist
Hospital Sungai Buloh
Sungai Buloh, Selangor

Dr. Mazapuspavina Md. Yasin
Senior Lecturer &
Family Medicine Specialist
Faculty of Medicine
Universiti Teknologi Mara, Selangor

Dr. Mohd. Aminuddin Mohd. Yusof
Head of CPG Unit
Health Technology Assessment Section
Ministry of Health

Dr. Nik Khairulddin Nik Yusoff
Head of Department &
Consultant Paediatrician (ID)
Hospital Raja Perempuan Zainab II
Kota Bharu, Kelantan

Dr. Norizzati Bukhary Ismail Bukhary
Family Medicine Specialist
Klinik Kesihatan Bandar Baru Bangi
Selangor

Dr. Philip Rajan
Otorhinolaryngologist (Otology)
Hospital Raja Permaisuri Bainun
Ipoh, Perak

Dr. Rafidah Mazlan
Senior Lecturer & Audiologist
Faculty of Health Science
Universiti Kebangsaan Malaysia
Kuala Lumpur

Dr. Roza Sarimin
Public Health Physician
Health Technology Assessment Section, MoH

Mr. Shahrom Ab. Rahman
Audiologist
Hospital Raja Perempuan Zainab II
Kota Bharu, Kelantan

Datin Dr. Siti Sabzah Mohd. Hashim
Head of Department & Senior Consultant
Otorhinolaryngologist (Paediatrics ORL)
Hospital Sultanah Bahiyah
Alor Star, Kedah

Dr. Sobani Din
Head of Department &
Otorhinolaryngologist (Otology)
Hospital Sungai Buloh, Sungai Buloh, Selangor

Mr. Suhaidie Manan
Assistant Medical Officer
Otorhinolaryngology Department
Hospital Kuala Lumpur, Kuala Lumpur

REVIEW COMMITTEE

The draft guidelines were reviewed by a panel of independent expert referees from both public and private sectors who were asked to comment primarily on the comprehensiveness and accuracy in the interpretation of evidence supporting the recommendations in the guidelines.

Chairperson

Dato' Dr. Abd. Majid Md. Nasir
Head of Department & Senior Consultant Otorhinolaryngologist
Hospital Kuala Lumpur, Kuala Lumpur

Members (alphabetical order)

Professor Dr. Din Suhaimi Sidek
Professor of Otorhinolaryngology & Senior Consultant Otorhinolaryngologist
School of Medical Science
Universiti Sains Malaysia, Kelantan

Dr. Hj. Md. Husain Hj. Said
Senior Consultant Otorhinolaryngologist
Sime Darby Medical Centre Subang Jaya, Selangor

Mdm. Noraini Mohamad
Senior Principal Assistant Director
Practice and Development Section
Pharmaceutical Services Division, Ministry of Health

Dr. Norzila Zainuddin
Senior Consultant Paediatrician (Respiratory Paediatrics)
Hospital Kuala Lumpur, Kuala Lumpur

Datin Dr. Rugayah Bakri
Deputy Director
Health Technology Assessment Section, Medical Development Division
Ministry of Health

Professor Dr. Siti Zamratol Maisara Mukhari
Professor of Audiology & Senior Consultant Audiologist, Faculty of Medicine
Pusat Perubatan Universiti Kebangsaan Malaysia, Kuala Lumpur

Dr. Sri Wahyu Taher
Family Medicine Specialist
Klinik Kesihatan Simpang Kuala, Alor Star, Kedah

Brigadier General Dato' Pahlawan Dr. Zulkaflay Abd. Rahman
Senior Consultant Otorhinolaryngologist
Hospital Angkatan Tentera Pangkalan TLDM, Lumut, Perak

EXTERNAL REVIEWERS (alphabetical order)

The following external reviewers provided feedback on the draft:

Dr. Hairel Anuar Selamat
Lecturer & Family Medicine Specialist
Medical Faculty, Cyberjaya University College of Medical Sciences, Selangor

Professor Dr. Henry Tan
Consultant Otorhinolaryngologist
KK Women's and Children's Hospital, Singapore

Dr. Matthew Yung
Consultant Otorhinolaryngologist
The Ipswich Hospital NHS Trust, Suffolk, United Kingdom

Dr. Mohd. Normani b. Zakaria
Lecturer & Audiologist
School of Health Sciences, Universiti Sains Malaysia

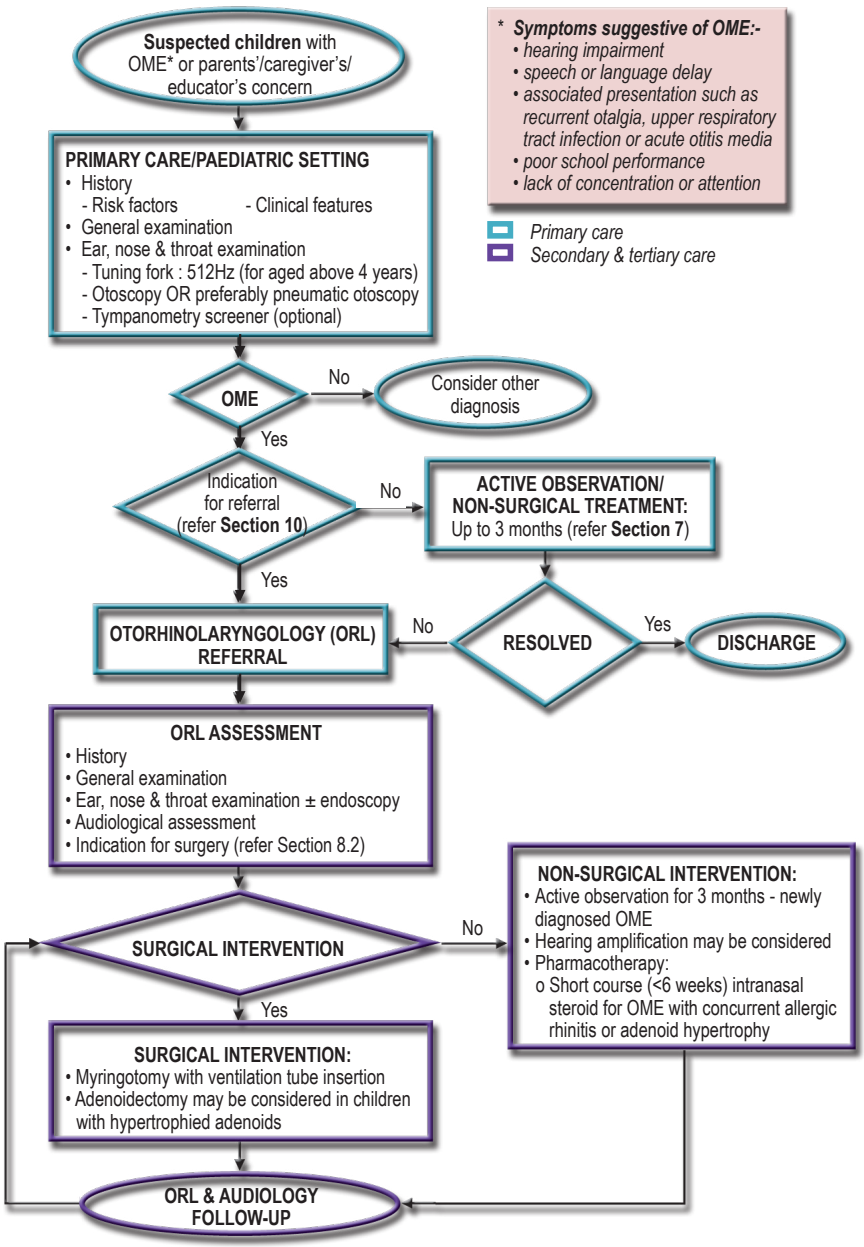
Dr. Nik Mazlina Mohamad
Family Medicine Specialist
Klinik Kesihatan Kajang, Selangor

Dr. Noor Khatijah Nurani
President
Malaysia Paediatrics Association

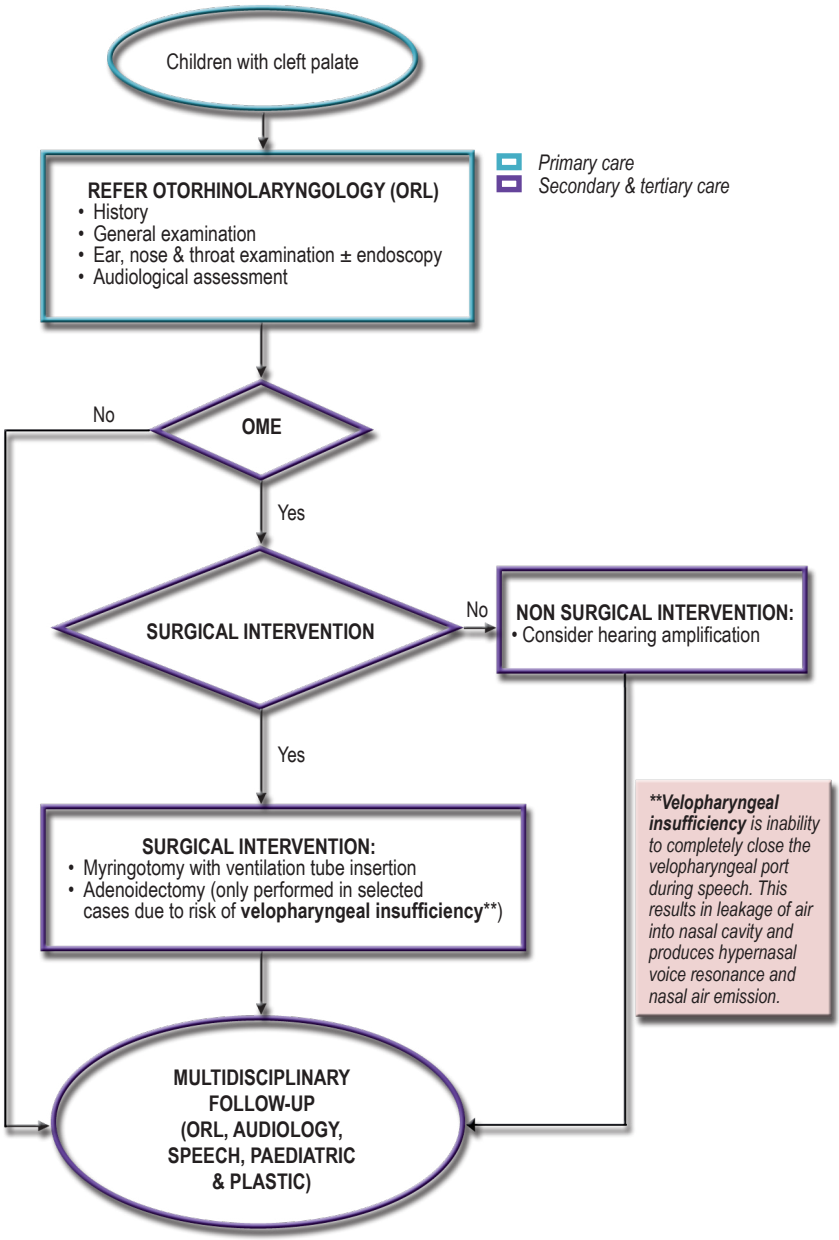
Pn. Nur Azyani Amri
National Head of Audiology Services
Hospital Sungai Buloh, Sungai Buloh, Selangor

Dr. Patrick Sheehan
Consultant & Honorary Senior Lecturer in Paediatric Otolaryngology
Royal Manchester Children's Hospital & North Manchester General Hospital / School of Medicine, University of Manchester, United Kingdom

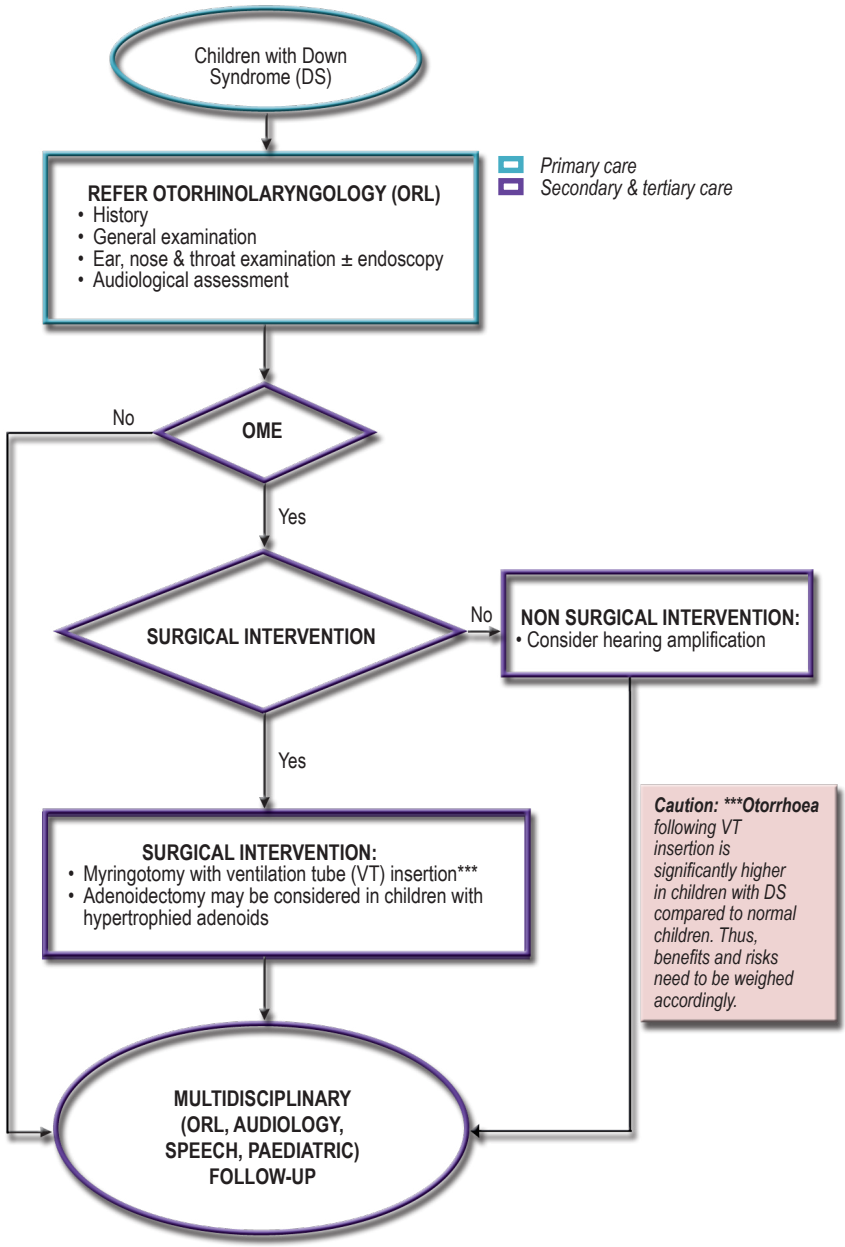
ALGORITHM 1: MANAGEMENT OF OTITIS MEDIA WITH EFFUSION (OME) IN CHILDREN



ALGORITHM 2: MANAGEMENT OF OTITIS MEDIA WITH EFFUSION (OME) IN SPECIAL CHILDREN (CLEFT PALATE)



ALGORITHM 3: MANAGEMENT OF OTITIS MEDIA WITH EFFUSION (OME) IN SPECIAL CHILDREN (DOWN SYNDROME)



1. INTRODUCTION

Otitis media with effusion (OME) is a condition characterised by a collection of fluid within the middle ear without signs of acute inflammation.

It is common in young children, with a bimodal peak at two and five years of age. Eighty percent of children have at least one episode of OME by the age of 10 years.[1] In Malaysia, the overall prevalence is 2.9% with an estimated cases of 761,962.[2, level III] These figures however may not reflect the actual disease burden as confirmatory testing could not be done in some children during the field survey. A study among preschoolers found that the prevalence rate of OME was 18.3%.[3, level IIII]

This disease is also a common ear problem among children especially those with craniofacial anomalies including cleft palate and Down syndrome (DS). A local study conducted in 1992 showed that the incidence of OME in children with cleft palate was 57.6%.[4, level III]

OME is known to be a fluctuating condition with symptoms that vary with time and age. However, the problem may persist in certain percentage of children. The main symptom of OME is impaired hearing.[1; 5, level III] This condition is often underdiagnosed, leading to untreated hearing impairment, which can cause speech and language developmental delay and poor school performance.[6]

While most cases of OME will resolve spontaneously, some children will need intervention in the form of educational and social action or the provision of hearing aids because of the effects of hearing loss.[1] Long-standing and untreated cases of OME may progress to serious conditions such as adhesive otitis media, ossicular chain disruption, retraction pockets and cholesteatoma.

Medical therapy has been widely used to treat the condition although evidence-based benefit has yet to be established. Surgical treatment options include myringotomy with or without ventilation tube (VT) insertion, adenoidectomy or both. Opinions regarding the risks and benefits of VT insertion vary and the management of OME therefore remains controversial.[7, level I; 8, level III]

The need for a local evidence-based CPG is timely due to variation in clinical practice, potential negative impact of OME on hearing and cognitive function, and to assist healthcare providers in the management of this condition.

2. EPIDEMIOLOGY

2.1 PREVALENCE

Prevalence of OME varies between 6.5% to 10.9% among children in different countries.[9, level II-2; 10, level III; 11, level II-3] Approximately 90% of children have OME at some time before school age, most often between six months and four years of age.[12, level III]

In Malaysia, findings from the National Hearing Survey for hearing and ear disorder in 2005 showed that the prevalence of OME was 5.1% in general population, 2.9% in children below ten years old and 2.6% in children aged 10 to 19 years.[2, level III] These findings may not reflect the actual prevalence of OME in children as the survey was conducted on general population including adults. A study by A. Saim *et al*. reported a OME prevalence of 13.8% among preschool children; it was higher in Kuala Lumpur (17.9%) compared to the district of Kuala Selangor (9.5%).[3, level III] Both studies reported higher prevalence among the Malays and other Bumiputera as compared to the Chinese and Indians communities.[2 - 3, level III]

2.2 RISK FACTORS

Significant non-medical risk factors for OME includes age (p<0.005), family size (p<0.01), sibling's history of OME (p<0.05), duration of breast feeding (p<0.05), season (autumn/winter/spring) (p<0.001), frequent swimming (p=0.034), and passive smoking (OR=1.46, 95% CI 1.21 to 1.76) after adjustment for nasal infection.[9, level II-2; 10, level III; 13 - 14, level II-2; 15, level III] However, gender and birth weight are not related to OME incidence.[14, level II-2]

Significant medical risk factors are previous acute otitis media (AOM) episodes (OR=5.75, 95% CI 2.60 to 12.69), nasal obstruction (OR=1.67, 95% CI 1.01 to 2.75) and acute tonsillitis (OR=1.68, 95% CI 1.00 to 2.80).[16, level II-2]

Children with unilateral cleft lip and palate (CLP) demonstrate higher prevalence of OME (74.7%) than those without cleft palate anomalies (19.4%) with p<0.001.[17, level II-2]

The prevalence of OME (based on otoscopy, tympanometry and age-appropriate audiometry) among children with DS range from 92% at age one to 73% at age five to six[18, level III] and 59% at age three.[19, level III]

In a local cohort study conducted in University Malaya Medical Centre among children with DS, 55% had type B tympanogram which reflected presence of OME.[20, level II-2] Another recent local study from Universiti Kebangsaan Malaysia Medical Centre found that out of a total of 224 DS children aged two months to 12 years old (mean 5.7 years), 71.4% had conductive hearing loss (CHL), 16.1% sensori-neural hearing loss (SNHL), 2.7% mixed hearing loss and 9.6% normal hearing. A total of 156 (69.6%) study subjects had type B tympanogram.[21, level III]

Other risk factors such as race, obesity, allergy and day care attendance show inconsistent relationship with OME.[9, level II-2; 13 - 14. level II-2; 22 - 23, level II-2]

Risk factors for developing OME

- Non-medical risk factors:
  - young age (two to five years old)
  - large family size
  - history of OME in sibling
  - short duration or no breast feeding
  - passive smoking
- Medical risk factors:
  - history of AOM
  - nasal obstruction
  - history of acute tonsillitis
  - craniofacial anomalies such as CLP and DS

3. SCREENING

As hearing loss is one of the disabilities caused by OME, hearing screening may play a role in detecting OME in children. However to date, no study have been identified on the role of opportunistic screening of OME and CHL in primary care. This is due to variation in timing of screening and screening algorithm such as age at testing, choice and combination of screening tools, type and training of the tester, setting, location, failure criteria, frequency and interval of retest.[1; 6; 8, level III; 12, level III; 24, level II-2]

Population-based screening for early detection of OME in asymptomatic children has not been shown to improve outcomes in terms of intelligence, receptive language or expressive language and thus has not been recommended.[8, level III; 12, level III; 14, level III; 24, level II-2]

- Screening for OME in general paediatric population is not recommended.

- Hearing assessment should be emphasised in the existing routine child developmental assessment to detect hearing loss.
- Hearing assessment may include distraction test, auditory and speech development (refer to **Appendix 3**), and otoacoustic emission.

Recommendation 1

- Otitis media with effusion should be ruled out in a child suspected of hearing loss. **(Grade C)**

4. CLINICAL PRESENTATION

Most children have middle ear effusions at some time during childhood which are transient and often asymptomatic with fluctuating hearing loss.[1; 6]

4.1 SYMPTOMS

Hearing impairment is the commonest presentation (90%) of OME at home or in school. The hearing impairment is of conductive type. Common associated presentations are otalgia (60%), upper respiratory tract infection/URTI (40%), AOM (30%) and tonsillitis (18%).[25, level III]

In children with OME, reasons for referral to hospital are speech problems (43%), hearing loss (41%) and speech delay (11%).[26, level II-3]

OME is an important cause of preventable hearing loss (57.1%), as compared to chronic suppurative otitis media (CSOM) and AOM (33.8% and 9.1% respectively).[27, level III] Hearing loss in children with OME may impair language and cognitive development. However, retrieved studies showed conflicting outcomes between OME and speech and language development.

A meta-analysis of cohort studies evaluated the association of early OME on various aspects of speech and language. Receptive and expressive language at preschool age (two to five years) were significantly better in controls than in children with OME.[28, level II-2]

Two papers showed harmful effects of OME on language development and academic performance. A study among urban Australian Aborigines with OME and hearing loss demonstrated a deleterious effect on the development of phonological awareness, reading and spelling performance in year one schooling (p<0.01).[29, level II-2] A local study by Khairi M *et al*. showed that poor academic performance was associated with mild hearing loss (p<0.001). OME accounted for 32.2% of the mild hearing loss group.[30, level III]

However, other studies showed no association between hearing loss due to OME and speech and language parameters in preschool children (p=0.67)[31, level II-2] or language development in the early school years (p<0.10).[32, level II-2] Roberts JE *et al*. similarly found no evidence of OME on later language, cognitive and academic performance during elementary school years.[33, level II-2 ; 34, level II-3]

Hooper *et al*. in their paper noted no association between children with OME-related hearing loss and attention outcomes. Further subanalysis showed those from poor home environments experienced greater difficulties on the attention tasks than those from good home environments (p<0.05).[35, level II-2] OME is a common cause of failed newborn hearing screening (64.5%).[36, level II-2]

Balance-related symptom often encountered in young children may result from chronic OME and this symptoms resolve following ventilation of the middle ear. In Bruininks-Oseretsky tests for stability, 61% of the study group performed below the expected scores for their age as compared to 7% of the controls (p<0.001). A difference was found between the results obtained before and after VT insertion in the tests (p<0.001).[37, level II-2] The presence of fluid in the middle ear impairs the condition of the balance system in children. Postural stability and the quantity of vestibulospinal reflexes seem to depend on the functional condition of the middle ear.[38, level II-2]

Allergic symptoms are not associated significantly with OME in children aged six to seven years, suggesting limited effect of allergy in the pathogenesis of OME in this age group.[39, level II-2]

Recommendation 2

- Otitis media with effusion (OME) should be ruled out in a child with any of the following symptoms:
  - hearing impairment
  - speech or language delay
  - associated presentation such as recurrent otalgia, upper respiratory tract infection or acute otitis media
  - poor school performance
  - lack of concentration or attention
  - balance difficulties **(Grade C)**

4.2 OTOSCOPIC FINDINGS

Normal otoscopy appearance showed pearly tympanic membrane (TM) with cone of light and normal position of handle of malleus (refer to **Appendix 4**).

The typical finding in OME is a dull TM due to distortion or loss of cone of light following retraction of the TM. The retraction of TM is mainly in the pars tensa with or without pars flaccida (attic or epitympanum) retraction. The other findings are the presence of fluid level and/or air bubble in the middle ear, variation in TM colour and immobility of TM on pneumatic otoscopy (refer to **Appendix 4**).

Retraction may be evident by indrawing handle of malleus or the presence of prominent annular fold. Colour changes can be yellow, amber or blue. Fluid level or air bubble is relatively uncommon.[40, level III] Opacity (p=0.001) and retraction (p=0.018) are the two characteristics of abnormal TM associated with elevated hearing threshold in OME.[5, level III]

- Otoscopic findings of OME:-
  - dull TM
  - retraction of TM
  - fluid level or air bubble
  - TM colour changes

Differences in clinical features and otoscopic findings between OME and other common middle ear diseases such as acute otitis media (AOM) and chronic suppurative otitis media (CSOM) are illustrated in table below.

Table 1: Clinical Features In Middle Ear Diseases

Clinical Features / Disease	Pain	Fever	Otorrhoea	Otoscopic findings
OME	No (unless with secondary infection)	No	No	• dull tympanic membrane (TM) • retraction of TM • fluid level or air bubble • TM colour change • restricted TM mobility with pneumatic otoscopy 
Acute otitis media (AOM)	Yes	Yes	Yes	• bulging TM • inflammed TM 
Chronic suppurative otitis media (CSOM)	No	No	Yes	• perforated TM • mucopurulent discharge 
Cholestetoma (URGENT REFERRAL)	No	No	Yes (scanty, foul smelling, persistent)	• attic or marginal perforation of tympanic membrane • presence of keratin debris 

4.3 PARENTAL SUSPICION

Parental suspicion of hearing loss has a low sensitivity (19.7%) and high specificity (97.0%), thus it is insufficient as a screening tool for the diagnosis of mild hearing loss caused by OME.[41, level II-2]

5. DIAGNOSTIC TESTS

A few methods have been used for the diagnosis of OME which include pneumatic otoscopy, tympanometry as well as acoustic stapedial reflex testing, otoacoutic emission and audiometry testing.

Rinne and Weber tuning fork tests have variable sensitivity and specificity in predicting conductive hearing loss associated with OME in children less than 12 years of age. This is due to children being less likely than adults to understand and complete the tuning fork tests.[42, level III]

The presence of effusion during myringotomy was used as a gold standard in the majority of studies in determining the test performance of each diagnostic tool.[43, level III; 44, level II-2; 45 - 47, level III; 48, level II-2] The sensitivity and specificity of each diagnostic tool were assessed.

5.1 OTOSCOPY

There is no retrievable evidence on the use of clinical otoscopy alone (without pneumatic component) in diagnosing OME in children. SIGN found no evidence on the most commonly used primary care diagnostic tool otoscopy (with or without tuning fork testing).[6] National Institute of Clinical Excellence (NICE) recommends otoscopy as part of clinical examination.[1]

5.2 PNEUMATIC OTOSCOPY

Pneumatic otoscopy is used to determine the appearance and mobility of the TM. It measures the mobility of TM by applying a positive and negative pressure through a pneumatic bulb that attaches to a standard otoscope.

A meta-analysis of cohort studies assessed the sensitivity and specificity of pneumatic otoscopy in predicting the presence of OME by comparing its outcomes with those of myringotomy. The results indicated that pneumatic otoscopy had a sensitivity of 94% (95% CI 92 to 96) and specificity of 80% (95% CI 75 to 86).[49, level II-2] In another study on a group of children aged one to ten years seeking medical treatment for suspected OME, the sensitivity and specificity of pneumatic otoscopy were 85% and 100% respectively. A similar study done among the Australian Aboriginal children revealed a sensitivity of 89% and a specificity of 69%.[50, level III]

Rogers *et al*. found that the test performance of pneumatic otoscopy are related to examiner's experience. In this study, the sensitivity and specificity of pneumatic otoscopy performed by staff pediatric otolaryngologist were 68% (95% CI 58 to 78) and 81% (95% CI 74 to 89) respectively as compared to 58% (95% CI 47 to 69) and 78% (95% CI 70 to 86) when performed by junior resident.[43, level III]

Earlier, Takahashi H *et al*. found that the aeration was correlated with the eardrum mobility (p<0.01). These results indicate that eardrum mobility was a good prognostic indicator of OME and best detected using pneumatic otoscopy.[51, level II-2]

Accuracy on the pneumatic otoscopy test was noted uniformly greater than accuracy with static test (otoscopy alone). The mean relative improvement in sensitivity and specificity from static viewing to pneumatic viewing were only 24% (95% CI 15% to 33%) and 42% (95% CI 27% to 58%) respectively. Accurate identification of both the presence and the absence of OME improved after pneumatic assessment of TM mobility.[52, level I]

5.3 ACOUSTIC IMMITTANCE MEASURES

Acoustic immittance measurement is an objective technique of assessing the integrity and function of the peripheral auditory mechanism.

Two commonly used acoustic immittance measures in clinical practice are tympanometry and acoustic stapedial reflex (ASR). Both tests offer a quick and objective assessment. They are routinely used to assess the status of the TM and middle ear system. In addition, these two tests have proven reliable measures for diagnosing middle ear pathologies in children and adults.[53, level III]

Conventional tympanometry and ASR tests (probe tone of 226 Hz) have become the standard practice in audiology clinics. However, the use of 226 Hz tympanometry is not recommended in infants aged less than seven months. In testing the middle ear function of young infants, a high frequency probe tone tympanometry (probe tone of 678 Hz and 1000 Hz) is recommended.[54, level III] This is because the infant's middle ear has a lower resonant frequency compared to older age group.[55, level III]

5.3.1 Tympanometry

Tympanometry is an objective test to measure acoustic admittance of the middle ear as a function of air pressure change in the external ear canal.[56, level III] It consists of the application of a probe tone of 226 Hz while the air pressure is changed within the ear canal. The resulting display is called a tympanogram which shows a variation of acoustic admittance against ear canal pressure.

Descriptions of the three common types of tympanogram are provided in **Appendix 5**.

A. Conventional (226 Hz) Tympanometry

Tympanometry with a frequency of 226 Hz was found to have high sensitivity and specificity in detecting OME in children aged one to ten years compared to higher frequency tympanometry. The results of 226 Hz tympanometry revealed a sensitivity of 80% and a specificity of 100%. Although the sensitivity for 678 Hz and 1000 Hz was high (95% and 100% respectively), the specificity for both frequencies was low at 54%.[45, level III]

In a multi-centre study involving 2,087 children, the sensitivity and specificity of Type B and Type C_2 tympanograms were investigated against various level of hearing (≥15 dB HL, ≥20 dB HL, ≥25 dB HL and ≥30 dB HL). The best combination to predict presence of OME with sensitivity and specificity of 81% was hearing level of ≥20 dB HL and Type B. However at the same hearing level, the inclusion of Type C_2 increased the sensitivity to 92% but reduced the specificity to 54%.[57, level II-1] Another study showed the sensitivity and specificity of Type B at hearing level of ≥25 dB HL were 90% and 68% respectively.[50, level III]

Using myringotomy as the gold standard, Nozza *et al*. found that the best tympanometric variable for detecting OME was tympanometric width >275 daPa as a fail criterion. The sensitivity and specificity of these diagnostic criteria were in the range of 78 - 89% and 81 - 100% respectively.[47, level III] In another study, the same authors found that using gradient of ≤0.1 and absent ASR provide the best combination for identifying OME with a sensitivity of 90% and a specificity of 86%.[48, level II-2]

B. High Frequency Tympanometry

i. 678 Hz Tympanometry

The use of 678 Hz tympanometry in cleft palate children aged between two and seven months demonstrated an agreement between Type B tympanogram and myringotomy findings in 96.3% of cases.[58, level III]

In a study conducted among 84 special care nursery neonates, 678 Hz tympanometry was found to be a useful diagnostic tool to measure the middle ear status in this group of children. Abnormal 678 Hz tympanograms was associated with failed transient evoked otoacoustic emission (p<0.0001) and absence of ipsilateral ASR (p=0.0002).[59, level III]

ii. 1000 Hz Tympanometry

Williams *et al*. compared tympanometry findings obtained using three different frequency probe tones in infants less than four months of age with otomicroscopy and pneumatic otoscopy results as the gold standard. The 1000 Hz tympanometry had the best agreement (κ=0.48 to 0.66) with the gold standard as compared to 678 Hz (κ=0.37 to 0.49) and 226 Hz (κ=0.11 to 0.23).[60, level III]

A study involving 52 infants with OME found that the agreement between computed tomography (CT) scan and 1000 Hz tympanometry was almost perfect (κ=0.961) while the agreement between CT and 226 Hz was poor (κ=0.103).[61, level III]

5.3.2 Acoustic Stapedial Reflex

The Acoustic Stapedial Reflex (ASR) test is usually performed following tympanometry to assess the function of the ear up to the brainstem region. This test involves the presentation of tonal and/or noise stimuli to elicit a reflex response from the stapedius muscle in the middle ear.[62, level III]

Absent of ipsilateral ASR is associated with abnormal 678 Hz tympanograms (p=0.0002) in detecting presence of OME in neonates.[59, level III]

The sensitivity of ASR is 88% when compared with both myringotomy and pneumatic otoscopy. While its specificity is 85% when compared with myringotomy and 82% with pneumatic otoscopy.[48, level II-2]

- Type B tympanogram is highly suggestive of OME.
- Type C_2 tympanogram combined with absence of ASR may also suggest OME.

5.4 PURE TONE AUDIOMETRY

Pure Tone Audiometry (PTA) is a behavioural test which is commonly used to establish hearing threshold across the range of audible frequencies. The results are plotted in a frequency vs intensity graph known as an audiogram. Description on the audiogram pattern is provided in **Appendix 5**.

In children referred for suspected OME, an association was found between PTA hearing thresholds and TM appearance obtained using pneumatic otoscopy. The mean PTA of patients with OME and bubble was lower than those without bubble (27.3 vs 37.4 dB HL, p=0.001).[5, level III]

In a study measuring PTA and 226 Hz tympanometry on subjects diagnosed with persistent OME, the mean six frequencies of PTA air conduction threshold (PTACT) was found to be greater in ears with Type B tympanogram than those with Type A tympanogram (29.3 dB HL vs 11.5 dB HL, p<0.001).[63, level III]

5.5 OTOACOUSTIC EMISSIONS

Otoacoustic emissions (OAEs) are sounds generated from the cochlea which can be recorded by a microphone fitted into the ear canal. Hence, this test is commonly used to determine cochlear status. In clinical setting, two types of acoustic stimuli are given to evoke the OAEs, which are transient evoked otoacoustic emissions (TEOAEs) and distortion product otoacoustic emissions (DPOAEs).

As OAEs are transmitted from the cochlea to the external ear canal via the middle ear, the condition of middle ear system directly influence the OAEs findings. Therefore, presence of effusion in the middle ear is associated with absent OAEs. Other cause of absence OAE is SNHL.

In two studies, high failure rates of OAEs were found in cases of abnormal tympanograms. TEOAEs were absent in 93.5% of children diagnosed with OME pre-operatively. Improvement of all TEOAEs parameters were found six weeks (p<0.01) and six months (p<0.01) post-operatively.[44, level II-3] An association between TEOAEs failure and abnormal tympanogram was noted in a group of special care neonates (p<0.0001).[59, level III]

Recommendation 3

- Otoscopy should be performed in suspected cases of otitis media with effusion (OME). Pneumatic otoscopy is preferred and should be made widely available. **(Grade C)**
- In all suspected cases of OME in places with trained personnel, the following tests should be performed:
  - Tympanometry (in infant less than seven months, high frequency tympanometry [678 Hz or 1000 Hz] should be used if available). **(Grade C)**
  - Pure Tone Audiometry (measurement of both air and bone conduction thresholds). **(Grade C)**

6. PREVENTIVE MEASURES

There are very few studies on prevention of OME in children. These studies are limited to the role of pneumococcal and influenza vaccination.

Two randomised controlled trials (RCTs) found that pneumococcal vaccination did not protect children against OME (OR=0.90, 95% CI 0.69 to 1.19).[64 - 65, level I] It also did not prevent recurrence of OME in those previously known to have persistent OME (RR=0.91, 95%CI 0.60 to 1.38).[66, level I] A subgroup analysis suggested benefit in children who had not been exposed earlier to the infection such as children with no older siblings (OR=0.58, 95%CI 0.38 to 0.91).[65, level I]

The role of influenza vaccine was studied in two prospective cohort studies. These studies which were conducted among young children attending day-care in temperate regions found that influenza vaccine was significantly effective in reducing OME episodes especially during influenza season.[67 - 68, level II-2] The effectiveness of the vaccine in tropical climate like Malaysia (where influenza season is not clearly identified) has not been studied. In addition, influenza vaccination requires yearly injection (to remain effective) and its cost-effectiveness locally need to be studied.

- Pneumococcal vaccination has no role in preventing otitis media with effusion (OME) as opposed to acute otitis media. Influenza vaccination is effective in preventing OME in temperate countries.

Avoidance of known risk factors such as passive smoking and bottle feeding could theoretically reduce the risk of developing OME. A meta-analysis of epidemiological studies found that passive smoking increased risk of middle ear disease by 35% (OR=1.35, 95% CI 1.23 to 1.49) for household smoking and 46% (OR=1.46, 95% CI 1.21 to 1.76) for maternal smoking.[69, level II-2] Formula-fed infants have 2-fold increase risk of first OME compared with infants breastfed for six months (RR=2.06, 95% CI 1.01 to 4.18).[70, level II-2] Although there is no direct evidence on modification to the above risk factors in reducing OME, breastfeeding and avoidance of passive smoking in children are advocated.

A cross-sectional study found that the risk of developing OME reduced by 40% in those taking regular chewing gums (OR=0.60, 95% CI 0.39 to 0.93).[71, level III] However, no further studies were identified to support this finding.

Recommendation 4

- Parents should be informed that breastfeeding for six months may reduce the risk of otitis media with effusion (OME) in their children. **(Grade C)**
- Parents should be advised that smoking may increase the risk of middle ear disease. **(Grade C)**

7. ACTIVE OBSERVATION

A systematic review (SR) examined the natural history and spontaneous resolution of OME in children. In children with newly diagnosed OME of unknown duration, the study found cumulative resolution rates of 56%, 72% and 81% at three, six and nine months respectively (using resolution criterion as change of tympanogram from type B to non-B). Lower resolution rates were also noted using other criteria for resolution. In contrast, children with documented chronic (defined as >3 months) bilateral OME had much lower resolution rates (19%, 25% and 31% at three, six and twelve months respectively).[72, level II-2]

A few RCTs examined the role of early vs delayed VT insertion. Some of the trials involving children with persistent but uncomplicated OME found prompt insertion of ventilation tube (VT) as compared to delayed insertion (nine months) did not measurably improve speech, language, cognition and psychosocial developmental outcomes.[73 - 77, level I]

However, two trials conducted in more severely affected children [bilateral OME and significant hearing loss (25 - 75 dB) for >3 months] found some benefits from early VT insertion for expressive language, verbal comprehension and behavioural problems.[78 - 79, level I] The subtle benefits appeared to persist up to age seven to eight years.[80, level I]

A period of continued observation will allow resolution of many cases of OME without the need for surgical intervention. During this period, parents and caregivers should be given advice on strategies to limit the effects of hearing loss in the child.[6; 8, level III]

Active observation is a period whereby patient is being observed for three months following diagnosis prior to surgical intervention.

Advice on educational and behavioural strategies to minimise impact of hearing loss during active observation:-[6; 8, level III]

- Face the child when speaking
- Get the child's attention before starting to talk
- Reduce background noise to the minimal
- Speak clearly with normal rhythm and volume; use visual cues (such as hands and pictures) in addition to speech
- Read to or with the child (explain pictures and ask questions)
- Repeat words, phrases, and questions when misunderstood
- In the classroom, the child should preferably be seated in the front row or near the teacher

Recommendation 5

- Children with newly diagnosed otitis media with effusion (OME) should undergo active observation for at least three months from the time of diagnosis as spontaneous resolution of OME may occur. **(Grade A)**
  - Specific advice* to improve communication should be offered. **(Grade C)**
- Children with documented persistent OME (>3 months) and hearing loss should be considered for surgical intervention. **(Grade B)**

* Refer to yellow box above

8. INTERVENTION

Interventions in OME management consist of non-surgical and surgical interventions.

8.1 NON-SURGICAL INTERVENTION

OME is a common condition in children which is usually mild with spontaneous resolution occuring in 56% of cases at three months.[72, level II-2] However, it can be recurrent and persistent after that.

Non-surgical intervention is beneficial if it could speed the resolution of an episode of OME. Medical therapy has been commonly used in the practice as the first-line treatment with variation in the treatment of choice.

8.1.1 Steroids

Topical intranasal steroid is beneficial either alone or with antibiotic in treating OME at one month. At three months, there is conflicting evidence in its effectiveness. However, the findings are not statistically significant.[81 - 82, level I]

In a RCT on patients with OME and adenoid hypertrophy, intranasal steroid spray was found to be effective at six weeks (p<0.001).[83, level I]

A Cochrane review showed faster resolution of OME when oral steroid was used alone (OR=0.22, 95% CI 0.08 to 0.63) or in combination with an antibiotic (OR=0.37, 95% CI 0.25 to 0.56) at two weeks when compared to control. No evidence of benefit beyond two weeks of treatment was noted.[82, level I]

In another RCT, no difference was demonstrated in the resolution rates of OME at three months follow-up between steroid, antihistamine and antibiotic alone or in combination (p>0.05).[84, level I]

No significant or lasting adverse events have been reported on topical intranasal or short term oral steroid use.[81 - 82, level I] However, prolonged use of oral steroid may lead to adverse side effects such as growth retardation.

Refer to **Appendix 6** for suggested medication dosages and side effects.

- Intranasal steroid **should not be used** for children less than two years old.

8.1.2 Antibiotics

Use of antibiotics leads to significantly lower rates in persistent OME in both ears and one or both ears in the antibiotic group (53% and 77%) compared to the controls (84% and 93%) after two weeks of follow-up.[85, level I]

However, a meta-analysis of 16 RCTs failed to support the continued use of antibiotics in the treatment of OME. Placebo-controlled trials did not show antibiotic efficacy (RD=0.043, 95% CI -0.001 to 0.086).[86, level I]

Short term use of antibiotics with oral steroid led to a faster resolution of OME as compared to antibiotic alone (OR=0.37, 95% CI 0.25 to 0.56).[82, level I]

Both NICE and SIGN guidelines do not recommend the use of antibiotics in children with OME.[1; 6]

8.1.3 Antihistamine or Decongestant

As OME may occur with allergic rhinitis, antihistamine and decongestant are widely used as symptomatic treatment in children with OME in the local practice.

However, a Cochrane SR in 2006 on children with OME showed no benefit of its use:[87, level I]

- Decongestant alone did not resolve OME at one month or less (RR=1.06, 95% CI 0.92 to 1.22).
- Antihistamine or combination with decongestant up to three months also did not resolve OME compared to placebo with RR=0.94 (95% CI 0.65 to 1.36) and 0.97 (95% CI 0.89 to 1.04) respectively.
- Neither antihistamine, decongestant nor the combination treatment lessened hearing loss at one month (RR=1.08, 95% CI 0.93 to 1.27) or one year (RR=1.50, 95% CI 0.63 to 3.56). All the treatment groups reported more side effects at or before one month (RR=2.70, 95% CI 1.37 to 1.88).

An update of the above review in 2011 showed no statistical or clinical benefit on the use of antihistamine or decongestant.[88, level I]

Both NICE and SIGN guidelines do not recommend use of antihistamine and decongestant in children with OME.[1; 6]

- Continuous use of topical intranasal decongestant more than two weeks may lead to rhinitis medicamentosa.

8.1.4 Autoinflation

A SR on autoinflation in children with OME showed no improvement in tympanometry and audiometry outcomes:[89, level I]

- Tympanometry at less than one month (RRI=1.65, 95% CI 0.49 to 5.61) or longer than one month (RRI=1.89, 95% CI 0.77 to 4.67)
- Audiometry (WMD=7.02, 95% CI -6.92 to 20.96)

8.1.5 Homeopathy and Mucolytic

There is no good quality evidence for homeopathy and bromhexine in children with OME.

8.1.6 Hearing Aid

Hearing aid is an option to amplify hearing in OME. It is generally acceptable to parents and children as it provides a non-invasive way of managing the problems associated with OME.[90 - 91, level III] However, there is no evidence to support its use as the first line of treatment in children with OME.

Hearing aid should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.[1] However, potential noise trauma is the main concern associated with continuous use after resolution of OME.[92, level III]

- There is **no role of topical ear drops** in treating otitis media with effusion (OME).

Recommendation 6

- Short term (less than six weeks) intranasal steroid can be used for otitis media with effusion (OME) with concurrent allergic rhinitis and adenoid hypertrophy. **(Grade A)**
- In children with OME, the following treatment is not recommended:
  - oral steroid **(Grade A)**
  - prolonged intranasal steroid **(Grade A)**
  - antibiotic **(Grade A)**
  - antihistamine or decongestant **(Grade A)**
  - autoinflation **(Grade A)**
  - homeopathy and mucolytic **(Grade C)**
- Hearing aids may be considered in persistent bilateral OME and hearing loss where surgery is contraindicated or not acceptable. **(Grade C)**

8.2 SURGICAL INTERVENTION

The main reason for considering surgery in OME is persistence of hearing loss. It is conducted to improve hearing and minimise the risk of OME recurrence.

The mainstay of surgical intervention is myringotomy with VT insertion to ventilate the middle ear. This will lead to normalisation of middle ear pressure. The choice of surgical intervention must be balanced between its risks and benefits.

Certain medical diseases such as bleeding disorder and other medical conditions which render patient unfit for general anaesthesia should be ascertained prior to surgery.

8.2.1 Timing of Surgical Intervention

OME exhibits a fluctuating pattern in its presentation and a number of cases will resolve spontaneously. The duration of the disease at first presentation is often uncertain. Thus, the decision for surgical intervention in OME is based on several factors such as duration of disease and presence of structural or functional complication.

Different guidelines and studies vary in their recommendations on timing of surgical intervention. Waiting time of three to six months before the intervention on persistent disease with hearing impairment of more than 25 dB or structural changes to the tympanic membrane is recommended.[1; 8, level III; 93, level III; 94, level II-2]

In children with significant hearing loss (>25 dB for three months or more), there is some benefit from VT insertion in expressive language, verbal comprehension and behavioural problems.[78 - 79, level I]

Recommendation 7

- Surgical intervention should be considered after three months of persistent otitis media with effusion with:
  - hearing loss >25 dB (at three frequency average) **(Grade A) AND/OR**
  - *structural changes to the tympanic membrane or middle ear. **(Grade C)**

* Refer to **Appendix 4**

8.2.2 Options of Surgical Intervention

A. Myringotomy

There is no retrievable evidence on myringotomy alone in the management of OME.

B. Myringotomy with VT

VT improves the hearing level in persistent bilateral OME. The effect of VT on hearing is significantly improved by 9 - 10 dB in the first six months compared to watchful waiting (WW) and diminishes but remains significance after this period.[95 - 97, level I] The improvement in hearing is greater in those with hearing threshold of >25 dB compared to <25 dB.[98, level I]

Patients with VT have shorter mean time with effusion (p=0.0001)[98, level I] and fewer bilateral OME in all visits[97, level I] up to 12 months of follow-up compared to WW group.

Improvement in hearing level in children with VT is better in those aged ≤3 years attending day-care and those aged ≥4 years with a hearing level of ≥25 dBHL in both ears persisting for at least 12 weeks.[98, level I]

There is no statistically significant difference in developmental outcomes such as language, cognitive, behaviour and quality of life in VT insertion compared with WW.[95 - 96, level I]

The percentage of functioning VT in situ reduce over time from 92% to 30% (from three to 12 months follow-up).[97, level I] Phosphorylcholine-

coated fluoroplastic VT do not offer any advantages over uncoated standard fluoroplastic tympanostomy tubes.[99, level I]

Repeated VT insertion for recurrent AOM or OME early in life will not be detrimental in the long-term hearing outcome.[100, level II-2]

C. Myringotomy with VT plus adenoidectomy

Adjuvant adenoidectomy along with VT insertion is routinely performed in many countries including Malaysia for recurrent episodes of OME and chronic persistent OME.

The benefit of adenoidectomy in reducing the recurrent AOM or persistent OME was found in patients with hypertrophied adenoids abutting the torus tobaris (p<0.05). However, adenoidectomy had no significant benefit in the nonabutting group.[101, level I] A cohort study showed that VT with adenoidectomy or adenotonsillectomy reduced risk of further VT surgery (p<0.001)[102, level II-2]

A meta-analyses showed that VT alone gave 6 to 9 dB hearing improvement compared to an additional of 1 to 4 dB in VT with adenoidectomy.[96, level I]

Adenoidectomy in young children aged 24 - 47 months does not add any further benefit in the reduction of OME recurrence and average rates of AOM or otorrhoea episodes, and requirement of additional surgical procedure.[103, level I]

D. Long-term VT

Long-term VT may be indicated when short term VT and additional measures such as adenoidectomy to improve eustachian tube function fail. It should be used in selective and individualised basis as the rate of complications such as recurrent otorrhoea and persistent perforation is high.[104 - 105, level III] A meta analysis of cohort studies showed that long-term tube increased the risk of perforation (RR=3.5, 95% CI 1.5 to 7.1) and cholestetoma (RR=2.6, 95% CI 1.5 to 4.4) compared to short term tube.[106, level II-2]

E. Other options

Laser myringotomy is a safe method to treat chronic OME in children and can be performed under local anaesthesia. However, laser myringotomy alone is a less effective treatment than myringotomy with VT.[107, level I]

Refer to **Appendix 7** on Advice to Parents of Children Post-Ventilation Tube

Recommendation 8

- Myringotomy with ventilation tube (VT) insertion is the treatment of choice for surgical treatment in otitis media with effusion (OME). **(Grade A)**
- Myringotomy with VT insertion combined with adenoidectomy should be considered in children with persistent OME and hypertrophied adenoids abutting the torus tobaris. **(Grade A)**

8.3 COMPLICATIONS OF VENTILATION TUBE INSERTION

Complications of VT can be divided into early and late complications.

8.3.1 Early Complications

The prevalence of otorrhoea is 4.9% to 15% in children less than 13 years of age with myringotomy and VT.[108, level III; 109, level II-2]

Another complication with myringotomy and VT is OME recurrence which has a prevalence of 11.2%.[108, level III] This complication is related to extrusion time of VT. The longer the extrusion time, the lower is the recurrence rate. The rate is 36.5% in group with retention time <6 months, compared to 17.7% in 6 - 12 months group (p=0.02) and 9.1% in >12 months group (p=0.001).[110, level III]

8.3.2 Long-Term Complications

The prevalence of myringosclerosis is 32.3% in children aged 3 to 16 years. Initial age of VT insertion and gender are not significant factors for the development of myringosclerosis after extrusion of VT.[110, level III]

VT increases the prevalence of myringosclerosis and late atrophy[109, level II-2; 111, level II-2] but these do not significantly affect hearing.[112, level II-1] Frequency of VT insertion is associated with increased prevalence of myringosclerosis, retraction pocket and negative tympanometric peak pressure (p=0.002, p=0.01, and p=0.008 respectively). However, the sequalae of VT such as myringosclerosis, atrophy, TM perforation and hearing loss typically developed earlier rather than later in disease and its treatment.[111, level II-2]

Following VT extrusion, the prevalence of residual TM perforation is only 1.7% to 3.0%.[100, level II-1; 108, level III; 111, level II-2] In a study of 78 children aged 2 to 10 years with myringotomy and VT, the prevalence of late-onset otorrhea was 16.1%.[108, level III] Intra-operative saline irrigation of the middle ear has been described in a study as an effective mean in preventing post-operative purulent otorrhea (p<0.005).[113, level I] However, this is not practiced in local setting.

- Recurrence of OME is part of the disease process which may occur at any point of time and not a complication of VT insertion.
- Advices to patients post-VT insertion:-
  - Keep ear dry
  - Use ear plug when swimming or bathing (especially when washing hair using shampoo or soap)
  - Do not insert object into the ear

8.3.3 Management of Complications

There is no specific treatment for myringosclerosis,[110, level III] as it does not significantly affect hearing.[112, level II-1]

Children with residual perforation should be considered for myringoplasty. In a cohort study, Yung M *et al*. found no difference in the surgical outcome between the younger age group (4 to 8 years) and the older age group (9 to 13 years) (p=0.23).[114, level II-2] However in another study, this operation was more likely to fail in younger children (p<0.0047) and those with anterior TM perforation (p<0.0038).[115, level III] Fat plug myringoplasty is an option for small perforation.[116, level II-3] In the local clinical practice, myringoplasty is offered to children above the age of 10.

In post-VT otorrhoea with recurrent acute otitis media, topical antibiotic is effective in children under three years of age with tube associated otorrhea. Systemic oral antibiotic is indicated in the presence of fever and otalgia. It is preferable to perform a bacterial culture of the discharge before commencing antibiotics.[113, level I; 117, level I]

There is no retrievable evidence on when to remove VT in cases of persistent otorrhoea. In the current practice, VT is removed when there is persistent otorrhoea despite optimum medical treatment.

Recommendation 9

- Myringotomy and ventilation tube (VT) insertion should be offered to children with otitis media with effusion as it is a **safe procedure**. **(Grade C)**
- Myringoplasty may be considered in residual perforation of TM in children. **(Grade C)**
- In post-VT otorrhoea, topical and oral antibiotic should be instituted. **(Grade A)**
  - Following failure antibiotic treatment, removal of VT should be considered. **(Grade C)**

9. MANAGEMENT OF OME IN SPECIAL CHILDREN

9.1 CHILDREN WITH CLEFT PALATE

Children with unilateral cleft lip and palate demonstrate higher prevalence of OME (74.7%) than those without clefts (19.4%) with $p<0.001$.[118, level II-2] A local study by Sakinah MS in 2007 found the prevalence of OME in cleft palate children at 55.4%.[119, level III]

In children with cleft palate, failure of palatal fusion during development results in abnormal insertion of the tensor veli palatine and levator veli palatine muscles in the soft palate. This will lead to improper opening of the eustachian tube which compromises ventilatory and muco-ciliary clearance functions of the middle ear. Thus it predisposes the children to early onset of OME. Despite palatal repair surgery, the functions of the eustachian tube cannot be completely restored. Therefore these children are at risk of persistent and longer course of OME.

OME in children with cleft palate is often intervened by early insertion of VT to improve hearing impairment, speech and language development, and to prevent long-term sequelae.

All children with cleft palate should be managed by a multidisciplinary team comprising of professionals from otorhinolaryngology (ORL), audiology, speech therapy, paediatrics, plastic and reconstructive surgery, maxillo-facial surgery, occupational therapy and medical genetics disciplines, and social welfare department.

9.1.1 Timing of VT

At six years follow-up, a cohort study of early placement of VT before the age of seven months for both cleft palate and control groups showed that hearing level improved with means PTA of 8.9 dBHL and 7.7 dBHL respectively.[120, level II-2] However in a recent SR of 18 papers with various study design and quality, there was inconsistent evidence to support the beneficial effect of early routine insertion of VT for treatment of OME in children with cleft palate.[121, level I]

Good compliance to hearing aid was associated with good hearing, speech and language development in 51.6% of children with cleft palate either with or without VT. However, those with VT (38.4%) were also found to have higher otological complications such as TM perforation and persistent otorrhea compared to those without VT

(4.5%) with $p<0.005$.[122, level III] In another study, there was no difference noted in otological outcomes (healed TM, retracted TM, perforated TM, persistent OME and VT in situ) when comparison was made between cleft palate and non-cleft group ($p=0.2$).[120, level II-2]

9.1.2 Hearing Threshold for VT

There is no good evidence retrieved on hearing threshold level to decide on VT insertion in children with OME and cleft palate. However in local practice, the threshold level to intervene is similar with normal children with OME.

9.1.3 Numbers of VT

Children with cleft palate often require multiple insertions of VT. Means number of VT insertions per ear are 1.7 and 2.1.[122, level III; 123, level II-2] Greater number of VT insertions are associated with abnormal TM appearance ($p<0.05$) and reduced hearing ($p<0.05$).[123, level II-2]

9.1.4 Use of Long-Term VT

There is no evidence to support the use of long-term VT in children with cleft palate at the first VT insertion.[122, level III; 123 , level II-2]

9.1.5 Hearing Screening

Newborns with cleft palate are at higher risk of failing newborn hearing screening compared with healthy neonates. Those who fail hearing screening have higher incidence of permanent CHL or SNHL compared to those who pass (43% vs 3%).[124, level II-2]

The incidence of SNHL in ears with OME in CLP or cleft palate children is 1.8%.[123, level II-2] Factors predicting persistent hearing impairment include cleft palate alone, female and presence of an associated syndrome.[124, level II-2]

9.1.6 CLP or cleft palate with associated syndrome

Associated syndrome is seen in 15.7% to 38.0% of CLP or cleft palate children[122, level III; 124, level II-2] with 5.4-fold higher risk of hearing loss ($p=0.05$) compared to those without associated syndrome.[124, level II-2] Thirty percent of infants with cleft palate and CLP associated syndrome may have underlying SNHL.[125, level II-2]

Recommendation 10

- All children with cleft palate should be managed by a multidisciplinary team. **(Grade C)**
- Hearing assessment should be performed early and six-monthly in all children with cleft palate or cleft lip and palate (CLP). **(Grade C)**
- Early ventilation tube insertion should be performed at the time of palatal repair in cleft palate or CLP infants with auditory brainstem response threshold level of ≥25 dBHL and after otological assessment. **(Grade C)**
- Hearing amplification may be considered as an option in cases of mixed (conductive and sensorineural) and moderate hearing loss in children with cleft palate. **(Grade C)**

9.2 CHILDREN WITH DOWN SYNDROME

Down syndrome (DS) is the most common genetic disorders and occuring in about 1 in 600 to 1 in 1000 live births. The incidence of DS in Hospital Kuala Lumpur, Malaysia was 1 in 950 live births. The incidence among Malays was 1 in 981, Chinese 1 in 940 and Indians 1 in 860.[126 - 127, level III] Various studies have shown that children with DS had higher incidence of OME. Clin Mol Teratol.[18 - 19. level III; 20, level II-2; 21, level III]

Characteristically, children with DS have mid-face hypoplasia, malformation of the eustachian tube, narrow nasopharynx, delayed motor development, generalised hypotonia and delayed maturation of immune system. These factors not only predispose them to develop OME at early age but also persistent and longer episodes of OME.

In a retrospective study, the mean age of children with DS diagnosed with OME referred to ORL clinic was 3.6 years (range 2 - 8). In these children, the diagnosis of OME was the commonest secondary finding (63.7%) and primary diagnosis of OME was only made in 17.2% of cases.[128, level III]

Children with DS have a significant higher incidence of hearing loss than the general population (37 - 78% vs 2.5%) and OME is the most common cause of hearing loss among them. In this group, even a mild degree of hearing impairment can have major consequences on speech perception and language development.[129, level III]

9.2.1 VT insertion

In a cohort study conducted in Japan, the mean age of VT insertion in children with DS was 5.4 ± 2.4 years (range 2 - 13).[130, level II-2] In a later study, 83% had first placement of VT at a younger age (range 6 and 18 months).[131, level II-2]

Many children with DS require multiple insertions of VT up to five times.[128, level III] Slightly more than half need more than single VT insertion (42.5% require two, 7.5% three and 5% four times).[131, level II-2] The mean interval between the first insertion and last extrusion of VT is 22.9±15.9 months in children with DS as compared to 27.5±23.6 months in normal children.[130, level II-2]

Persistent hearing loss after VT insertion was noted higher in children with DS (40%) when compared to normal children (9%).[132, level II-2] However in another five-year longitudinal study, 98% of children with DS achieved normal to borderline normal hearing level after meticulous surgical or medical treatment. The study concluded that early diagnosis and aggressive treatment, started soon after birth, provided improvement in hearing.[133, level II-2]

Otorrhoea following VT insertion was found higher in children with DS compared to normal children (p<0.01). Similarly, the incidence of complications after extrusion of VT (cholesteatoma, permanent perforation and atelectasis) was also higher among them than normal children (p<0.05).[130, level II-2] Another study showed that seven of 11 children with DS had persistent otorrhoea after VT insertion with limited improvement in hearing.[134, level III] Following VT extrusion, only 26% children with DS had normal TM appearance or slight retraction as compared to 78% in normal children (p<0.05).[130, level II-2]

VT insertion in children requires general anaesthesia and can be done as day care surgery. However, it is not suitable for children with DS due to risk of developing complications such as poor oral intake and upper airway obstruction.[128, level III]

The following factors should be considered in the child before VT is offered as an option to hearing aids:[1]

- severity of hearing loss
- age
- practicality, risks and chances of early extrusion of VT

9.2.2 Hearing Amplification

Forty percent of children with DS have stenotic ear canals and 80% of them have OME. Fitting of hearing aid in the stenotic ear canals is a challenge and even when it is well-fitted, it can be difficult to achieve compliance among them.[135, level III]

Hearing aids should normally be offered to DS children with hearing loss.[1] There is no retrievable evidence to compare the benefits of conventional hearing aids to VT among children with DS and OME.

Bone conduction hearing aids and bone anchored hearing aid (BAHA) are other forms of hearing amplification methods. Two studies showed that OME was the second most common indication for BAHA after chronic otitis media among children with DS. Most patients and parents were satisfied with the result of better hearing with BAHA. Both studies concluded that BAHA had a role in overall management of children with DS after conventional hearing aids and/or ventilation tubes had been considered.[134, level III; 136, level III]

Recommendation 11

- All children with Down syndrome (DS) should be managed by a multidisciplinary team. **(Grade C)**
- Hearing assessment should be performed early and six-monthly in all children with DS. **(Grade C)**
- Hearing amplification should be considered in children with DS who have otitis media with effusion (OME) and either:
  - stenotic ear canal
  - mixed hearing loss
  - as an alternative to VT where necessary **(Grade C)**
- VT should be considered in DS with OME after weighing its risks and benefits. **(Grade C)**

10. REFERRAL

To date, there is lack of direct evidence on referral of children with OME. Therefore, recommendations are derived from several existing guidelines, local expert consensus and other sections of these CPG.[1; 6; 8, level III; 12, level III; 137, level III]

Recommendation 12

- Children with **any of the following features** should be referred to an otorhinolaryngologist for diagnosis and management of otitis media with effusion (OME):
  - hearing impairment or hearing loss due to uncertain causes
  - recurrent episodes of acute otitis media or otalgia
  - speech and language development not appropriate for age
  - impaired social or educational development and behavioural symptoms (lack of concentration or attention) associated with hearing impairment
  - underlying craniofacial anomalies, Down's Syndrome and cleft lip and/or palate
  - otoscopic findings such as colour changes, opacity or retraction of tympanic membrane and presence of fluid level or air bubble persisted after three months of active observation. **(Grade C)**
- Children with persistent OME after active observation for three months should also be referred to ORL. **(Grade C)**
- **URGENT REFERRAL** is required in the presence of **cholesteatoma** (refer to **Appendix 4**). **(Grade C)**

- **Features of cholesteatoma**
  - Persistent, scanty, foul-smelling ear discharge
  - Attic or marginal perforation of tympanic membrane
  - Presence of keratin debris
  - Hearing impairment

11. PARAMETERS TO BE MONITORED DURING FOLLOW-UP

There are parameters that need to be monitored during follow-up of children with OME following treatment. They are TM appearance, presence of ear discharge, hearing level, middle ear impedance and speech and language development, education and behaviour.

11.1 OTOLOGICAL FINDINGS

Majority (67.3%) of the VT-treated ears are healed after five years of follow-up.[112, level II-2] However, common abnormalities that have been reported are TM atrophy, myringosclerosis, TM retraction and otorrhea. Less common abnormalities include TM perforation, persistent OME and VT in place.[111 - 112, level II-2; 138, level II-2]

- In post-VT, the presence of the following abnormalities require ORL consultation:
  - Otorrhea
  - TM retraction
  - TM perforation
  - Persistent hearing loss (this may be due to SNHL or ossicular erosion)

11.2 AUDIOLOGICAL FINDINGS

Audiological tests in combination with otoscopic examination play a major role in diagnosing OME. The tests are as follows:

11.2.1 Pure Tone Audiometry

PTA shows improvement in hearing with mean difference of 10.3 dB after myringotomy at five years follow-up (p<0.001). TM perforations, ongoing episodes of OME and pars tensa retractions are associated with mild conductive hearing loss (p<0.0005). Atrophy and myringosclerosis of TM are not associated with hearing impairment.[112, level II-2]

11.2.2 Tympanometry

In a cohort study, an eight years follow-up post-VT showed the prevalence of low static admittance (SA) and broad-peaked tympanograms (Type B) declined from 38% to 8%, while high SA and narrow peaked tympanograms (Type A) increased from 23% to 64%.[111, level II-2]

11.2.3 Auditory Brainstem Response

Auditory Brainstem Response (ABR) is only available at certain hospitals with audiology services.

ABR techniques are useful in estimating hearing loss in children with OME who are difficult to be tested by behavioural audiometry.[139, level II-2]

Following VT insertion, ABR shows improvement in mean peak I, III and V latencies in the effusion present group (p<0.0001). Mean hearing loss improves from 22 dBnHL to 11 dBnHL after VT (p<0.0001).[139, level II-2]

11.3 SPEECH, LANGUAGE AND ACADEMIC DEVELOPMENT

RCTs conducted in children with severe OME children found some benefits from early VT insertion for expressive language, verbal comprehension and behavioural problems.[78 - 79, level I]

OME accounts for 32.2% of mild hearing loss, which is associated with poor academic performance (p<0.001).[30, level III]

Recommendation 13

- Children with otitis media with effusion (OME) should be followed-up for otological and audiological assessment regularly. **(Grade C)**
- Children with OME post-ventilation tube should be followed-up within the first month of surgery followed by six-monthly interval till recovery. **(Grade C)**

12. LONG-TERM SEQUELAE

There is no established time frame as to what constitutes long-term sequelae. In **Section 4** on clinical presentation, structural changes and functional disability have been discussed in length.

The search for evidence on the long-term sequelae of OME without any intervention provides no retrievable results. This is likely due to the fact that the attending physician will intervene in cases with structural or functional deficits to prevent complications.

Despite VT insertion, there is evidence of long-term structural and functional sequelae. In a cohort study, organised OME (granulation or cyst) in the mastoids on CT scan three months after VT insertion was associated with a higher incidence of attic retraction, sclerotic and poorly pneumatised mastoids ($p<0.05$). However, the study population consisted of both children and adults.[140, level II-2]

In another study on patients who had VT insertion during their childhood, higher prevalence of severe retraction ($p=0.02$), severe atrophy and hearing loss ($p<0.01$) was noted after 9 to 23 years compared to four years after treatment.[141, level III]

A review found that 20% of patients with cholesteatoma had a past history of OME with VT insertion. Evolution of OME into cholesteatoma occured in not more than 0.5% of OME cases, whether or not VT were inserted.[142, level III]

- OME can result in long-term structural changes to the tympanic membrane and middle ear (such as severe retraction, cholesteatoma and poorly developed mastoids) and functional impairment (such as hearing loss).

13. IMPLEMENTING THE GUIDELINES

In assisting healthcare provider and patient in the management of specific clinical circumstances, it is important not only to develop valid CPG by a sound methodology, but also to ensure the implementation of the evidence-based recommendations in it. There is often a gap between the development and implementation into practice of a CPG.

Each implementation strategy is effective under different circumstances and a multifaceted approach is most likely to achieve change. The approach should be tailored to suit local circumstances and address local barriers. Successful strategies to change practice need to be adequately resourced including people with adequate knowledge and skills. Team work and co-operation between primary and secondary/ tertiary care is paramount to achieve this.

13.1 EXISTING FACILITATORS AND BARRIERS

Existing facilitators for application of the recommendations in the CPG include:

a. Hearing assessment in child developmental assessment in the primary care and the School Health Programme
b. High Risk Newborn Hearing Screening Programme in hospitals with ORL and audiology services
c. Universal Newborn Hearing Screening in selected hospitals
d. Database on OME based on National Hearing Registry

Existing barriers for application of the recommendations of the CPG include:

a. Poor understanding/limited knowledge of OME
b. Inadequate training during undergraduate and housemanship training
c. Insufficient resources in diagnosing OME
d. No specific data registry on OME

13.2 POTENTIAL RESOURCE IMPLICATIONS

To implement the recommendations in the CPG, the following factors are identified to have potential resource implications:

a. Widespread distribution of the CPG to healthcare personnel via printed copies
b. Re-enforce training of healthcare personnel especially in primary care via regular seminars or workshops to ensure active dissemination of information

c. Improve resources to diagnose OME including trained personnel and diagnostic and assessment tools such as:
   i. pneumatic otoscope, noise stick and tympanometry screener should be made available in all health clinics, School Health Team and paediatric clinics. Although pneumatic otoscope is a good instrument and easily used, it is not available in all centres. Additional cost is implicated if a new set or an accessory to the existing otoscope is required.
   ii. multifrequency tympanometry and OAE/ABR screener should be made available or adequate in all centres with audiology service.
d. Develop multidisciplinary teams at secondary/tertiary care level in the management of OME with CLP or DS
e. Facilitate the provision of hearing amplification device to the required group of children with OME
f. Strengthen the database of OME as part of the National Hearing Registry

To assist in the implementation of the CPG, the following are proposed as **clinical audit indicators for quality management**:

- Percentage of hearing assessment in children with cleft palate/CLP/DS = $\frac{\text{Number of children with cleft palate/ CLP/DS screened for hearing in a year}}{\text{Total number of children with cleft palate/ CLP/DS diagnosed in the same period}}$ x 100%

- Percentage of children with documented persistent OME (>3 months) and hearing loss undergo myringtomy and VT = $\frac{\text{Number of children* with newly diagnosed persistent OME (>3 months) with hearing loss undergo myringtomy and VT in a year}}{\text{Number of children with newly diagnosed persistent OME (>3 months) with hearing loss in the same period}}$ x 100%

* children: excluding Down syndrome

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Appendix 1

SEARCH TERMS

The following MeSH terms or free text terms were used either singly or in combination:

"Otitis Media with Effusion"[Mesh] OR "middle ear effusion" OR "glue ear" OR "serous otitis media" OR "secretory otitis media" OR "OME" AND "prevalence" OR "incidence", "risk factors", "Down Syndrome", "cleft palate", "prevalence" OR "incidence" OR "risk factors", AND "screening programme" OR "mass screening" OR "screening method", "sensitivity and specificity", AND "clinical presentation" OR "symptom" OR "sign" OR "hearing loss" OR "hearing impairment", OR "deafness" OR "hypoacusis" OR "hypoacuses" OR "conductive hearing loss" OR "poor school performance" OR "poor educational progress" OR "speech delay" OR "delayed language development" OR "indistinct speech" OR "language development disorder" OR "speech development disorder" OR "semantic pragmatic disorder" OR "poor school performance" OR "speech delay" OR "behavioral problems".

"Otitis Media with Effusion"[Mesh] OR "middle ear effusion" [All Fields] OR "glue ear" OR "serous otitis media" OR "secretory otitis media" OR "OME" AND "tympanometry" OR "impedance audiometry" OR "impedance acoustic test", "acoustic admittance", "pure tone audiometry", "acoustic reflex", "pneumatic otoscopy", "otoscopy","tuning fork tests", "Rinnes and Webers test", AND "observ*" OR "watchful waiting" OR conservative OR "natural history" AND "prevent*" OR "prevention" OR "preventive measure" , "Vaccine" OR "vaccination" OR "immunization" OR "immunization" , "Smok*" OR "tobacco" OR "cigarette", "breastfeed*" OR "breastmilk", "pacifier" OR "teat" OR "dummies" OR "soother", "xylitol" OR "chewing gum".

"Otitis Media with Effusion"[Mesh] OR "middle ear effusion" [All Fields] OR "glue ear" OR "serous otitis media" OR "secretory otitis media" AND "Steroids"[Mesh] OR "oral steroid" OR "nasal steroid", "antibiotic" OR "antimicrobial"OR "antibacterial" OR "antibacterial prophylaxis" OR "amoxycillin" OR "clavulanic acid" OR "macrolide" OR "cephalosporin", AND "mucolytic agent" OR "Acetylcysteine", AND "supplement" OR "vitamin", AND "homeopathy" OR "herbs" OR "acupuncture" OR "traditional medicine" OR "complementary medicine", AND "autoinflation device" OR "hearing aids" OR "probiotics", AND "antihistamine" OR "decongestant".

“Otitis Media with Effusion”[Mesh] OR “middle ear effusion” [All Fields] OR “glue ear” OR “serous otitis media” OR “secretory otitis media” AND “time of surgery” OR “timing” OR “time of intervention”, AND “surgery” OR “myringotomy”OR “myringotomy with ventilation tube” OR “adenoidectomy” OR “adenoidectomy and myringotomy with ventilation tube”. “Middle Ear Ventilation”[Mesh] OR “ventilation tube” AND “serous otitis media” OR “middle ear effusion” OR “secretory otitis media” OR “glue ear” OR “ventilation tube” AND “adverse event” OR “complication”.

“cleft palate”[MeSH] AND “Otitis Media with Effusion”[Mesh] OR “glue ear” OR “serous otitis media” OR “middle ear effusion” OR “secretory otitis media. Otitis Media with Effusion”[Mesh] OR “glue ear” OR “serous otitis media” OR “middle ear effusion” OR “secretory otitis media” AND “down syndrome” “[MeSH]. “Otitis Media with Effusion”[Mesh] OR “Middle Ear Ventilation”[Mesh]OR “Otitis Media with Effusion”[Mesh]OR “glue ear” OR “serous otitis media” OR “middle ear effusion” OR “secretory otitis media” OR “OME” AND ”Referral and Consultation”[Mesh] OR “Physician Self-Referral”[Mesh]. “Otitis Media with Effusion”[Mesh] OR “glue ear” OR “serous otitis media” OR “middle ear effusion” OR “secretory otitis media” AND “follow up” OR “audiological test” OR “hearing assessment” OR “Auditory Brainstem Response”.

Appendix 2

CLINICAL QUESTIONS

A. INTRODUCTION

1. What are the epidemiological characteristics and risk factors for OME in children?
2. What is the role of screening for OME in children?

B. ASSESSMENT AND DIAGNOSIS

1. What are the clinical presentations or symptoms suggestive of OME in children?
2. How to diagnose a child with OME?
3. What is the test performance of the various method of diagnosis? (Diagnostic tests: tuning fork test, otoscopy, pneumatic otoscopy, pure tone audiometry (PTA), tympanometry)

C. PRINCIPLES OF MANAGEMENT

1. What is the role of preventive measures?
2. What are the treatment options?
   - 2.1 Non surgical intervention
     - 2.1.1 What is the role of active observation?
     - 2.1.2 What are the roles, clinical effectiveness and safety of various non surgical interventions? (steroids, antihistamine and/or decongestants, antibiotics, autoinflation, hearing aids)
   - 2.2 Surgical intervention
     - 2.2.1 When is the appropriate time for surgical intervention?
     - 2.2.2 What is the clinical effectiveness of various surgical procedures:
       - i. Myringotomy
       - ii. Myringotomy with ventilation tube
       - iii. Myringotomy with ventilation tube and adenoidectomy
       - iv. Other options
     - 2.2.3 What are the complications of ventilation tube insertion and their management?
   - 2.3 How OME in children with Down's syndrome and cleft palate be managed?

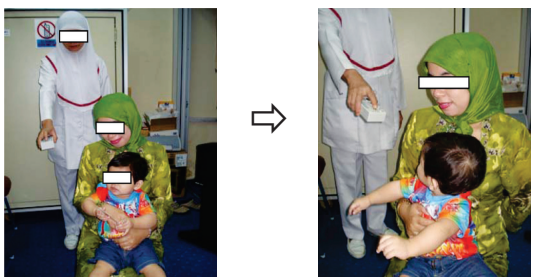
D. REFERRAL AND FOLLOW-UP

1. When should a patient with OME be referred to an otorhinolaryngologist?
2. What parameters are to be monitored during follow-up?
3. What are the long-term sequelae in OME patients?

Appendix 3

THE CONDUCT OF A DISTRACTION TEST

The Distraction Test is a behavioural hearing test which is used as a screening tool for babies of six to nine months. It may also be used with older children if they are still at the developmental stage for the test. Test techniques may have to be modified but the rigour must be maintained.



- The child is required to sit on the parent's lap.
- Different signals, like speech sounds /s/, /sh/ and /m/, sounds generated by noise stick, high frequency rattle, chime bar, drum, cup and spoon are presented randomly at 0.5 to 1 meter distance, next to the child's ears.
- Sharp and reliable head-turn responses or eye movements towards the direction of sound source are expected to be noted during the test.
- The sound levels presented should be monitored and checked using a sound level meter.

Sources:

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AUDITORY AND SPEECH DEVELOPMENT

Chronological age	Hearing development	Speech development
In utero	• hearing develops early in fetal development and is fully functioning at birth	-
Birth - 3 months	• smile or quiet when hear sounds • startle when hear loud noise	• babble “ooing” or “yooing”
4 - 6 months	• moving the eyes to the direction of sound give different respond to various sounds	• smiles at familiar faces e.g. parents
7 months - 1 year	• turning head to the direction of sound	• imitates different sounds
1 - 2 years	• identify body parts when asked	• saying **one** word e.g. “mama”, “baba” or “mummy”
2 - 3 years	• understanding two words instruction e.g. go toilet	• uses **two** words sentences meaningfully e.g. “nak makan”
3 - 4 years	• can answer simple question for common activities, e.g. playing ball • points to common objects described by their use	• uses **three** words or more • names familiar environmental sounds • asks questions, e.g. what is this/that?
4 - 6 years	• answer simple ‘how?’ questions • tell two events in order of occurrence • answer ‘why?’ question with an explanation	• uses **four** word sentences or more • able to carries on a simple conversation • uses last night oryesterday and tommorrow meaningfully • able to tell a simple story

Appendix 4

OTOSCOPIC APPEARANCE OF OME

Pneumatic otoscopy

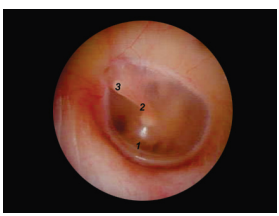


Fig. 1 Normal otoscopy of Left Tympanic Membrane (TM)

Translucent pearly white TM with a cone of light reflex at the anterior-inferior quadrant:

1. *Cone of light at the antero-inferior quadrant*
2. *Handle of malleus*
3. *Lateral process of malleus*

Otoscopic findings in Otitis Media with Effusion (OME)

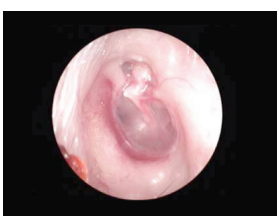


Fig. 2a Retracted Left TM
Prominent lateral process of malleus and attic retraction

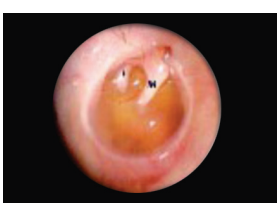


Fig. 2b Fluid in the right middle ear
The TM is retracted with a prominent malleus (M) and incus (I) with dullness of TM and loss of light reflex. The middle ear cavity is filled with fluid (below the red dotted line)

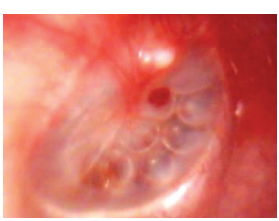


Fig. 2c Fluid with air bubbles in the right middle ear

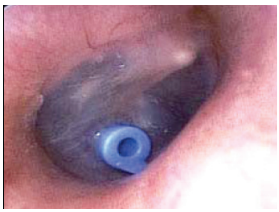


Fig. 3 Right TM with VT in-situ

Otoscopic findings of other common middle ear diseases

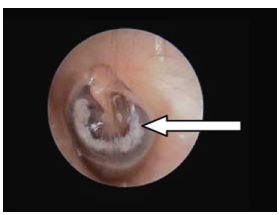


Fig. 4 Myringosclerosis of left TM
Chalk-white patches on the TM (arrow)

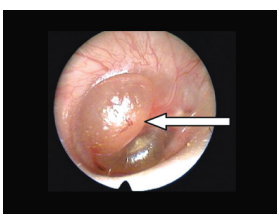


Fig. 5 Acute otitis media
The TM is bulging and inflamed (arrow). Patient may present with otalgia, fever and URTI. As disease progress, the TM may rupture resulting in mucopus otorrhoea and pain relief.

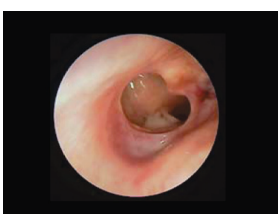


Fig. 6 Perforated TM
Large central perforation of left TM

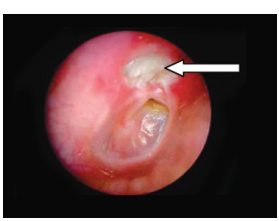
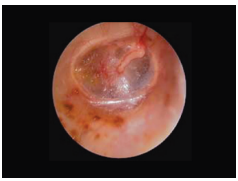


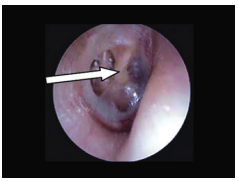
Fig. 7 Cholesteatoma of Right Ear
Foul smelling discharge with whitish keratin debris from an attic (superior) perforation (arrow). This case needs urgent referral.

Images courtesy of Dr. Philip Rajan, Dr. Sobani Din,
Assoc. Prof. Dr. Rahmat Omar & Prof. Dr. Prepageran Narayanan

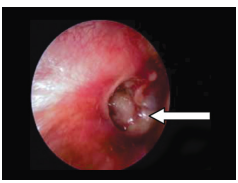
CLASSIFICATION OF PARS TENSA RETRACTION (SADE)



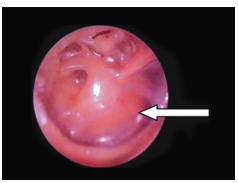
Grade I
Slight retraction of the TM over the annulus



Grade II
The TM touches the long process of the incus (arrow)

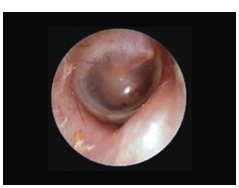


Grade III (Atelactasis)
The TM touches the promontory (arrow)

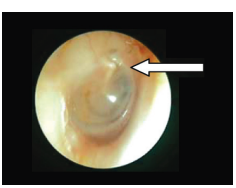


Grade IV (Adhesive)
The TM is adherent to the promontory (arrow)

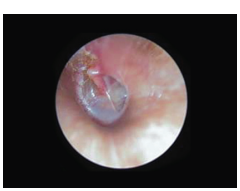
CLASSIFICATION OF PARS FLACCIDA RETRACTION (TOSS)



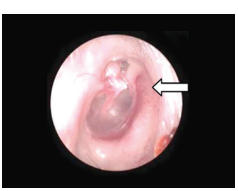
Grade 0
Normal right TM



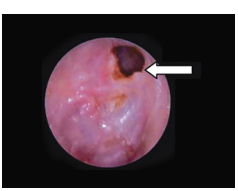
Grade 1
Slight dimple of pars flaccid, not touching the neck of malleus (arrow)



Grade 2
Pars flaccida (Shrapnell's membrane) retracted maximally & draped over the neck of the malleus (arrow)



Grade 3
Stage 2 + erosion of the scutum (outer attic wall)

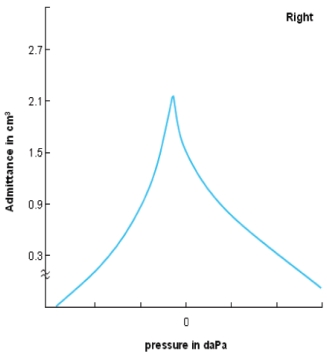


Grade 4
Full blown retraction pocket (arrow). Deep retraction, keratin cannot be reached by suction clearance.

Appendix 5

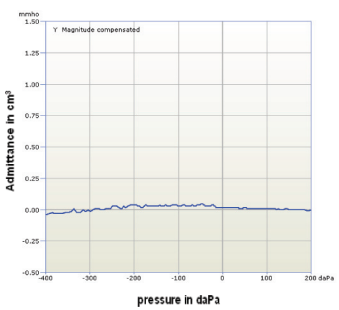
TYPES OF TYMPANOGRAM
(Jerger Classification 1970)

1. Type A tympanogram



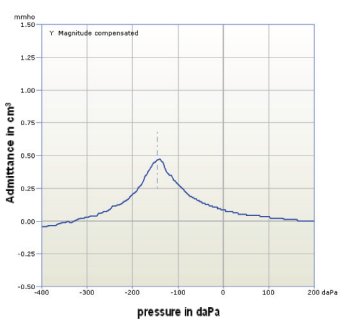
In type A, the peak compliance occurs at/or near atmosphere pressure (0 daPa) indicating normal pressure within the middle ear.
This indicates normal middle ear pressure.

2. Type B tympanogram



In type B, there is no sharp peak (flat) with little or no variation in the impedance.
This indicates presence of fluid in the middle ear (OME), tympanic membrane perforation or ear wax occluding the external ear canal.
In OME, the ear canal volume is normal.

3. Type C tympanogram

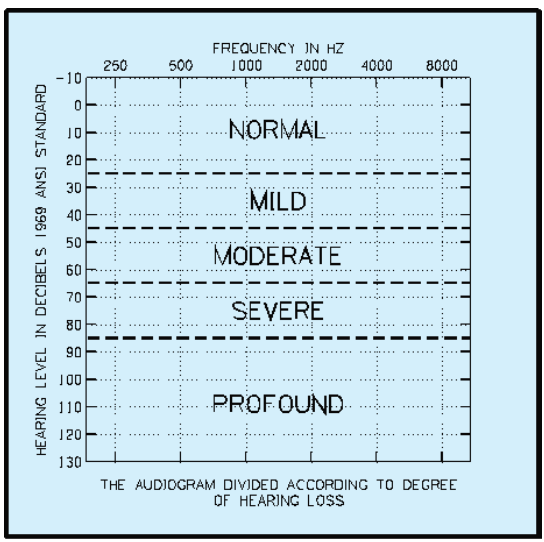


In type C, the peak compliance is significantly below 0 (usually ≤ -150 daPa) indicating negative pressure within the middle ear.
This indicates Eustachian tube dysfunction.

AUDIOGRAM

The audiogram is a graph showing the results of the pure-tone hearing tests. It illustrates the type, degree and configuration of hearing loss.

The frequency or pitch of the sound is referred to in Hertz (Hz). The intensity or loudness of the sound is measured in decibels (dB). The responses are recorded on a chart called an audiogram that shows intensity levels for each frequency tested.



Sources:

- American Speech-Language-Hearing Association (ASHA) Working Group on Aural Acoustic-Immittance Measurements, Committee on Audiologic Evaluation. Tympanometry. Available from http://www.asha.org/docs/pdf/RP1988-00027.pdf
- American Speech-Language-Hearing Association (ASHA). Audiometric Symbols. Available from http://www.asha.org/docs/html/GL1990-00006.html

Appendix 6

LIST OF MEDICATION DOSAGES AND SIDE EFFECTS IN CHILDREN WITH OTITIS MEDIA WITH EFFUSION

Drug Class	Drug	Recommended Dosages	Side Effects	Cautions and Contraindications	Comments
Steroids	Intranasal Mometasone Furoate	1 spray (50 mcg) in each nostril daily	Headache, cough, viral infection, epistaxis	May cause suppression of hypothalamic-pituitary-adrenal axis, particularly in younger children or in patients receiving high doses for prolonged periods	Not recommended to be used in children below 2 years old
	Intranasal Beclomethasone Dipropionate	6 - 12 years of age: start with 1 spray (42 mcg) in each nostril twice daily; may increase to 2 inhalations in each nostril.	Epistaxis, localised Candida infection	May cause growth retardation in children	Not recommended for children below 6 years of age
	Intranasal Fluticasone Furoate	1 spray (27.5 mcg) in each nostril daily (TDD = 55 mcg). Can increase to 2 sprays in each nostril daily (TDD=110 mcg)	Nasal ulceration, epistaxis, cough, nausea		Not recommended for children below 2 years of age

Source:

- Lacy C, Armstrong LL, Goldman MP. Drug Information Handbook International (18th Edition). Hudson: Lexi-Comp; 2006

Appendix 7

INFORMATION FOR PATIENT ON MYRINGOTOMY AND VENTILATION TUBE INSERTION

What is myringotomy?

A myringotomy is the making of a small opening in the tympanic membrane (eardrum). The operation is performed through the ear without external incision.

What is a ventilation tube (grommet)?

A ventilation tube is a small tube (ranging from 1.04 - 1.54 mm in diameter) which is inserted onto the tympanic membrane.

Why does a child need this operation?

This operation is performed to ventilate (aerate) the middle ear, to drain the middle ear fluid and to prevent the fluid reaccumulation. This should improve the hearing if the hearing loss is due to OME.

How long does the ventilation tube stay in-situ?

It depends on the type of ventilation tube. The short term ventilation tube usually will come out on its own after 3 to 6 months.

What type of anaesthetic will a child require?

The operation is usually performed under general anaesthesia.

What should be expected after the operation?

The child may be drowsy for a few hours post-operatively.

What are the risks and consequences after the operation?

Most operations are safe; however there is a small chance of side effects/complications such as:

- **Ear pain**
  There will be slight discomfort or mild ear pain which will usually subsides within 1 - 2 days and does not require analgesics. Paracetamol can be given for analgesia.

- **Discharge from ears**
  Minimal blood-stained discharge may be present for a few days. If mucopurulent discharge occurs, medical attention is required.

- **Side effects of anaesthesia**
  The child may feel drowsy, nauseated and vomiting due to the anaesthetic medications.

- **Fever**
  A low grade fever (less than 38^0C) is normal after surgery.

What are the post-operative instructions?

- Do not insert anything into the ear canal to clean the discharge. Outer ear can be wiped with clean and dry cloth.

- The ears should remain dry. Avoid water entering the ears by plugging the ear with vaseline-smeared cotton or ear plug while taking bath. Swimming should be avoided for a few weeks. After that, children are encouraged to wear ear plugs and a properly-fitting cap whenever they are swimming.

- Most children can return to day care or school once they are fully recovered from the anaesthetic effect.

- A child who develops upper respiratory tract infection should be managed the usual manner. Minimal clear ear discharge can be expected.

- There is no contraindication for air travel. The ventilation tube will protect the ears from any pressure-related pain

When should the child seen by a doctor?

- High grade fever of more than 38^0C

- Continuous ear bleeding or discharge

- Severe pain not relieved with analgesics

LIST OF ABBREVIATIONS

ABR	auditory brainstem response
AOM	Acute Otitis Media
ASR	acoustic stapedial reflex
CHL	conductive hearing loss
CI	confidence interval
CLP	cleft lip and palate
CPG	clinical practice guidelines
CSOM	Chronic Suppurative Otitis Media
CT	computed tomography
daPa	dekapascal
dB	decibel
dB HL	decibel hearing level
dBnHL	decibel normalised hearing level
DPOAE(s)	distortion product otoacoustic emission(s)
DS	Down syndrome
Hz	hertz
mcg	microgram
MoH	Ministry of Health
NICE	National Institute for Clinical Excellence
OAE(s)	otoacoustic emission(s)
OME	Otitis Media with Effusion
OR	odds ratio
ORL	Otorhinolaringology
PTA	pure tone audiometry
PTACT	PTA air conduction threshold
RC	Review Committee
RCT(s)	randomised controlled trial(s)
RD	risk difference
RR	relative risk
RRI	relative risk of improvement
SA	static admittance
SIGN	Scottish Intercollegiate Guideline Network
SNHL	sensorineural hearing loss
SR	systematic review
TEOAE(s)	transient evoked otoacoustic emission(s)
TM	tympanic membrane
TDD	total daily dose
URTI	Upper respiratory tract infection
vs	versus
VT	ventilation tube
WMD	weighted mean difference
WW	watchful waiting

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Malaysia Health Technology Assessment Section (MaHTAS)
Medical Development Division,
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Federal Government Administrative Centre
62590, Putrajaya, Malaysia