Chronic suppurative otitis media

Burden of Illness and Management Options

Child and Adolescent Health and Development
Prevention of Blindness and Deafness

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Foreword

Chronic suppurative otitis media (CSOM) is a major cause of acquired hearing impairment in children, especially in developing countries. Most approaches to treatment have been unsatisfactory or are very expensive and difficult; for example parenteral aminoglycosides require long hospitalization and are potentially ototoxic. This situation is reflected in the IMCI recommendation only to wick the ear, but not to use any antibiotics. If the child continues to have a discharging ear on day 5 of follow-up, the consequence is to encourage further wicking. This is unsatisfactory, as the child's caretaker sees no real option for treatment, and may search for alternatives from other sources, spending money and losing trust in the health system. Recent developments in the treatment of chronic otitis media include evidence for the efficacy of antibiotics, especially with the introduction of topical quinolones, which are reported to have high effectiveness and are relatively easily administered, but remain expensive.

These questions are of interest to health workers throughout the world. The Department of Child and Adolescent Health and Development and the Team for Prevention of Blindness and Deafness at WHO have prepared this technical monograph which addresses the epidemiology and burden of CSOM in different countries, its diagnosis and consequences in individuals, and currently used management options and their cost-effectiveness. It proposes scenarios for management of the disease according to different presentations and an assessment is made of the feasibility and impact of each scenario.

It is hoped that the document will provide an overview of current knowledge about CSOM and a scientific basis for action, especially in developing countries.

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Summary

Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by a persistent discharge from the middle ear through a tympanic perforation. It is an important cause of preventable hearing loss, particularly in the developing world.

Prevalence surveys, which vary widely in disease definition, sampling methods, and methodologic quality, show that the global burden of illness from CSOM involves 65–330 million individuals with draining ears, 60% of whom (39–200 million) suffer from significant hearing impairment. CSOM accounts for 28 000 deaths and a disease burden of over 2 million DALYs. Over 90% of the burden is borne by countries in the South-east Asia and Western Pacific regions, Africa, and several ethnic minorities in the Pacific rim. CSOM is uncommon in the Americas, Europe, the Middle East, and Australia.

A history of at least 2 weeks of persistent ear discharge should alert primary health workers to the problem; if the ear could be dry mopped well enough to see the eardrum, then the diagnosis of CSOM can be confirmed by visualization of the perforation in the tympanic membrane. Field tests in Africa have shown that the accuracy of WHO's Integrated Management of Childhood Illness (IMCI) algorithm for "ear problem" varies across country settings. To help identify the disease at an early stage without unduly increasing the number of unnecessary referrals to specialists, the questions that health workers should ask and the procedures for visualizing the eardrum must be refined, standardized, and validated.

Before the management of any patient with CSOM one should take into account the fact that patients with intracranial or extracranial infections are more appropriately treated with surgery. Mastoidectomy with or without tympanoplasty eradicates mastoid infection in about 80% of patients and may be combined with surgical drainage of otogenic abscesses elsewhere. However, such treatment is costly and does not always lead to satisfactory hearing improvement, and is inaccessible in many developing countries.

Daily instillation of topical antiseptics or topical antibiotics after meticulous aural toilet for at least 2 weeks appears to be the most cost-effective treatment for the short-term resolution of otorrhoea. Topical quinolones are particularly effective in resolving otorrhoea without the risk of ototoxicity. There is no evidence that the addition of oral antibiotics confers increased benefit. Intravenous antibiotics, particularly the anti-pseudomonal drugs, are highly effective but too expensive.

Patients with CSOM may consult a doctor with one of the following: 1) a newly discharging untreated ear, 2) a persistently discharging initially treated ear, 3) a recurrently discharging ear, 4) a discharging ear with headache, fever, dizziness and other danger signs, or 5) a dry, perforated eardrum with hearing loss. The first two scenarios are best managed at the primary health care level by patiently questioning the child's carer, carefully examining the eardrum, and administering topical antimicrobials for 2 to 4 weeks. The type of antimicrobial and the route of administration should be selected to suit the specific infecting organism. Patients should be referred to a trained otoscopist to confirm the diagnosis. The third scenario requires careful assessment of the middle ear by an ENT specialist for middle ear disease that has not resolved. Antimicrobial therapy may still be initiated, but the patient must be given the benefit of otological assessment for possible elective mastoidectomy. Health care managers should consider organizing outreach ear clinics and ear camps in areas where patients of this type would not otherwise have access to specialized care. The fourth scenario requires urgent referral of patients with an intracranial or extracranial extension of CSOM to an ENT specialist for emergency mastoidectomy. The fifth scenario requires restoration of hearing either by tympanoplasty or by the use of a hearing amplification device.

Chapter 1
Global burden of disease due to chronic suppurative otitis media: disease, deafness, deaths and DALYs

Introduction

Definition of CSOM

Chronic suppurative otitis media (CSOM) is, for the purposes of this document, defined as a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges or otorrhoea through a tympanic perforation. The disease usually begins in childhood (85,114) as a spontaneous tympanic perforation due to an acute infection of the middle ear, known as acute otitis media (AOM), or as a sequel of less severe forms of otitis media (e.g. secretory OM) (40,169,170). The infection may occur during the first 6 years of a child's life, with a peak around 2 years (107). The point in time when AOM becomes CSOM is still controversial. Generally, patients with tympanic perforations which continue to discharge mucoid material for periods of from 6 weeks (93) to 3 months, despite medical treatment, are recognized as CSOM cases. The WHO definition requires only 2 weeks of otorrhoea (155), but otolaryngologists tend to adopt a longer duration, e.g. more than 3 months of active disease (68).

The ultimate fate of the tympanic perforation is still largely undocumented. Thus, both the start and the end of the disease process are difficult to define. Although healing is often observed over prolonged periods, there are more patients who develop either recurrent bouts of otorrhoea (active CSOM) or a dry but permanent tympanic perforation (inactive CSOM). Inactive otitis media refers to a previously discharging ear that has apparently ceased [discharging] without probability of resumption in the near future (111); the term is common among Asian colleagues. Often, the perforation heals imperfectly with areas of retraction and scarring in the eardrum which do not vibrate in response to sound, as well as normal areas.

The episodes of otorrhoea are often provoked by upper respiratory infections. This is particularly common in children. Soiling of the middle ear from swimming or bathing also leads to intermittent and unpleasant discharges. A decidedly smaller group of patients, particularly those who have not been treated, develop life-threatening complications.

Difference between CSOM and other forms of chronic otitis media

Several systems of nomenclature have been developed to distinguish between different types of otitis media, reflecting the lack of complete understanding of the processes responsible for the inflammation and healing of the middle ear. For the purpose of this report, the presence of a persistent tympanic perforation and middle ear discharge differentiates CSOM from other chronic forms of otitis media. CSOM is also called chronic active mucosal otitis media, chronic oto-mastoiditis, and chronic tympanomastoiditis. A subset of CSOM may have cholesteatomas or other suppurative complications. The non-CSOM group includes such entities as chronic non-suppurative otitis media, chronic otitis media with effusion (COME), chronic secretory otitis media, chronic seromucous otitis media, chronic middle ear catarrh, chronic serous otitis media, chronic mucoid otitis media, otitis media with persistent effusions, and glue ear. All these are recurrent or persistent effusions in the middle ear behind an intact tympanic membrane in which the principal symptom, if present at all, is deafness and not ear discharge (18,110).

Bacteriology of CSOM

CSOM can also be differentiated from AOM on bacteriological grounds. In AOM the bacteria found in the middle ear include *Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae* and *Micrococcus catarrhalis*. These are respiratory pathogens that may have been insufflated from the nasopharynx into the middle ear through the Eustachian tube during bouts of upper respiratory infections. In CSOM the bacteria may be aerobic (e.g. *Pseudomonas aeruginosa, Escherichia coli, S. aureus, Streptococcus pyogenes, Proteus mirabilis, Klebsiella* species) or anaerobic (e.g. Bacteroides, Peptostreptococcus, Proprionibacterium) (23,25,56). The bacteria are infrequently found in the skin of the external canal, but may proliferate in the presence of trauma, inflammation, lacerations or high humidity (111). These bacteria may then gain entry to the middle ear through a chronic perforation (90). Among these bacteria, *P. aeruginosa* has been particularly blamed for the deep-seated and progressive destruction of middle ear and mastoid structures through its toxins and enzymes.

Histopathological features of CSOM

Otitis media presents an early acute phase, with essentially reversible mucosal and bony pathological changes, which continues to a late chronic phase with well established, intractable mucoperiosteal disease. The recurrent episodes of otorrhoea and mucosal changes are characterized by osteoneogenesis, bony erosions, and osteitis that include the temporal bone and ossicles (115). This is followed by ossicular destruction and/or ankylosis which, together with the tympanic perforation, contribute to the hearing loss (39,135).

Effects of deafness on child development

The hearing impairment produced by otitis media affects intellectual performance, which has been demonstrated by several studies. Long-term effects on overall intellectual, linguistic and psychosocial development have not been consistently observed. For instance, the Guidelines Panel of the Agency for Health Care Policy and Research, which developed clinical practice guidelines for otitis media with effusion, found inconsistent and often conflicting effects on expressive and receptive language, behaviour, and intelligence depending on the study design, the tests used, and the age at which the tests were administered (132). Among infants with cleft palate, those with unremitting chronic otitis media with effusion had pure tone thresholds 5 dB higher, as well as lower scores in psychological, emotional and social development test results, compared with those who underwent drainage of middle ear effusion. No such difference was found between otitis media-prone and non-otitis media-prone Apache Indian children.

CSOM produces mild to moderate conductive hearing loss in more than 50% of cases. This results from disruption of the eardrum and ossicles assembly (conductive hearing loss) or from hair cell damage by bacterial infection that has penetrated the inner ear (sensory hearing loss), or both (mixed hearing loss) (28,33). Because of its long duration and greater severity compared with acute otitis media, and because most children need louder auditory stimuli than adults to perform optimally (129), CSOM in children is likely to inhibit language and cognitive development. Several studies have linked persistent and significant hearing loss from otitis media (not just CSOM) during the first two years of life with learning disabilities and poor scholastic performance (161,162). Other studies have shown no effect (57,80). Differences in design, measurement and testing (e.g. the duration and severity of hearing loss in detecting otitis media), and in follow-up durations (e.g. in determining intellectual and language delays) may account for the inconsistency of the association among them (104). Lack of access to hearing aids aggravates the hearing disabilities. At a recent WHO meeting of experts from 15 African countries, CSOM was considered the most common cause of persistent mild to moderate hearing impairment among children and young people in developing countries. In Nairobi, Kenya, hearing loss was found in 64% of schoolchildren with CSOM and in only 3.4% of children without CSOM (155).

Complications of CSOM

CSOM produces chronic mastoiditis by contiguous spread (52). Erosion of the walls of the middle ear and mastoid cavity, which is rare, leads to exposure of the facial nerve, jugular bulb, lateral sinus, membranous labyrinth and temporal lobe dura. This in turn leads to such complications as facial nerve paralysis, lateral sinus thrombosis, labyrinthitis, meningitis and brain abscess (110,153). Contiguous or haematogenous spread of infection to the brain produces similar, permanently disabling and potentially fatal complications (91).

Risk factors for CSOM

The risk factors for the development of CSOM have not been clearly established in the available literature. The disease is less common than AOM and well-designed prospective cohorts that correlate pre-existing conditions with the incidence of CSOM are lacking (90). Much of what we know is based on studies of the predisposing factors to AOM, which the authors have extrapolated to CSOM. This is based on the observation that recurrent AOM may predispose to CSOM (58) and that 35% of children with recurrent AOM had chronic otitis media as well, compared with only 4% of children with less than five AOM episodes (77), although the much lower prevalence of CSOM suggests that persistence of infection is an exception rather than the rule. Another compelling piece of evidence is the decline of CSOM in the antibiotic era, suggesting that treatment of acute infections like AOM prevents progression to the chronic forms (5,19). However, the risk factors for AOM and CSOM may still be different from each other (78) and the associations are not consistent among studies (94). The multifactorial nature of otitis media must be stressed. Inadequate antibiotic treatment, frequent upper respiratory tract infections, nasal disease (66), and poor living conditions with poor access to medical care (59,85) are related to the development of CSOM (89,90,169,170). Poor housing, hygiene and nutrition are associated with higher prevalence rates, and improvement in these aspects was found to halve the prevalence of CSOM in Maori children between 1978 and 1987 (186). Proximity to a health care facility significantly reduced the otitis media attack rate among Arizona Indian children living in reservations (180). Bottle-feeding (184), passive exposure to smoking (3), attendance in congested centres such as day-care facilities (59), and a family history of otitis media are some of the risk factors for otitis media (3,79,93,184). The predisposition of certain races, such as the South-western American Indians (181), Australian Aborigines (158), Greenlanders (79), and Alaskan Eskimos (112), to CSOM is also well documented. These risk factors probably favour the development of CSOM by weakening the immunological defences, increasing the inoculum, and encouraging early infection (18).

Disease burden

Review of prevalence studies

Because of the chronic nature of the disease and because the point at which AOM changes to CSOM is unclear, prevalence seems a more appropriate indicator for measuring the disease burden. A MEDLINE search was conducted using the following terms: "chronic otitis media", "mastoiditis", "epidemiology" and "prevalence". The abstracts were screened and studies that reported prevalence rates, obtained from community surveys of the general population or surveys of special groups of subjects at risk (e.g. schoolchildren), were included. Full texts of all included studies were then sought. If no abstract was available but the titles suggested fulfilment of the inclusion criteria, or if an included abstract had no actual prevalence rates, then the full texts of the articles were also sought.

All the studies measured the prevalence rates, not the incidence rates (Table 1). None of the surveys mentioned the term CSOM or provided a definition similar to this report's definition of CSOM. The terms used ("chronic otitis media", "perforation" and "otorrhoea") did not appear to be synonymous.

Country prevalence rates were grouped based on the WHO regional classification. A ninth category was added, consisting of ethnic minorities that have had high prevalence rates of CSOM. Countries were then categorized by prevalence, as proposed by WHO during a WHO/CIBA workshop of otitis media experts in 1996 (186). CSOM prevalence rates of 1–2% were considered low and 3–6% were high; some racial groups had the highest CSOM rates (Table 1).

Table 1. Classification of countries according to CSOM prevalence

Group	Populations
Highest (>4%) – urgent attention needed to deal with a massive public health problem	Tanzania, India, Solomon Islands, Guam, Australian Aborigines, Greenland
High (2–4%) – avoidable burden of disease must be addressed	Nigeria, Angola, Mozambique, Republic of Korea, Thailand, Philippines, Malaysia, Vietnam, Micronesia, China, Eskimos
Low (1–2%)	Brazil, Kenya
Lowest (<1%)	Gambia, Saudi Arabia, Israel, Australia, United Kingdom, Denmark, Finland, American Indians

Table 2. Prevalance of CSOM, by region and country

Region/Country	Yr	Survey subjects	Chronic OM	Perfo-ration	Otorrhoea	Survey Coverage
Africa						
1. South Africa	85	267 children 0–15 yrs		0.4 (70)	0.4	Community
		>15 yrs		2.8 70)	1.4	
2. Nigeria	79	486 schoolchildren			0.6-3.6	
3. Kenya	92	544 schoolchildren	2.5-4.2		(30,131)	
	92	5368 schoolchildren	1.1	2.4 (73)	1.1 (8)	District
4. Angola	82	619 schoolchildren	3.4 (15)			Community
	88	854 schoolchildren	1.6 (16)		3.1	Community
5. Tanzania	80	3772 ENT patients	14 (108)			Clinic
	95	854 schoolchildren	1.6 (13)			Community
6. Gambia	83	2015 children 2-10 yrs	0.6 (114)			Nationwide
7. Mozambique	82	100 children 6 mo-5 yrs	2 (141)			Community
Eastern Mediterranean						
1. Saudi Arabia	92	6421 children 2 mo-12 yrs		1.5* (7)	0.2	City
2. Israel	89	2664 schoolchildren	0.3 (36)			School
	86	3056 10 yrs and older	0.95 (143)			Community
South-East Asia						
1. Thailand	86	0-15 yrs		4.7	2.6	Nationwide
		6-12 yrs		1.4	1.2	
		6-12 yrs		1.2	0.9	
2. Republic of Korea	81	4855 subjects	3.3 (128)			
		0-10 yrs	0.6(128)			Nationwide
		6-15 yrs	0.6(128)			
	93	9321 subjects all age groups	2.19 (94)			Nationwide
3. India	97	284 schoolchildren	7.8 (83)			School

Region/Country	Yr	Survey subjects	Chronic OM	Perfo-ration	Otorrhoea	Survey Coverage
Western Pacific						
1. Malaysia	90	1307 schoolchildren		4.4 (52)	2.5 (52)	School
2. Philippines	94	320 schoolchildren	3.2 (2)			District
3. Vietnam	97	3300 children		4.2 (42)		
4. Solomon Islands	84	0-5 yrs			6.1 (50)	Community
		0-15 yrs			3.8 (50)	
5. Guam	66			2.2-8.3(19)		
6. Micronesia	85	779 Pohnpeians				
		2 mos - 25 yrs		4 (45)	2.3 (46)	
		Belau children		10.6 (46)		Islandwide
		Yapese		4 (46)		
		Marshall Islands		2.8 (46)		
	87	554 Chuukese children 0-12 mo		10		Community
9. Australia	80	60 white children			3-7	School
10. China	97	90095 adults >65 yrs	0.3 (101)			Nationwide
		children	4			
Americas Brazil	90	259 schoolchildren	1.2 (14)			Community
Europe						
1. UK	83	Adults	0.6			Nationwide
	91	48313 adults	1.5 (26)			Nationwide
2. Denmark	85	>5yrs		0.2		Nationwide
3. Finland	97	All ages			Nearly 0 (5)	Nationwide
Special ethnic groups						
1. American Indians	85	Alaska		1.1		
		Montana		0.8		
		S. Arizona		0.4		
	84	15890 Navajo children		4 (127)	0.8 (125)	School
2. Alaskan natives	77	Eskimo children		2		
	78			9.3 (31)		
	86			9.7 (31)	28-43	
3. Australian Aborigines	80	153 children		10.2 (158)	5.7 (158)	
4. Greenland	84	3165 children**				Community
		11-20 yrs	8 (137)			
		41-50 yrs	2 (137)			

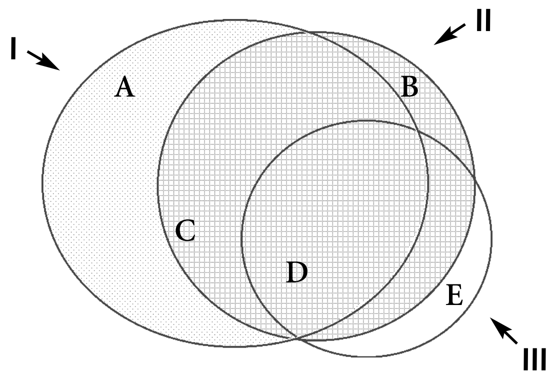
* Ninety-four out of 6421 children were reported to have "suppurative otitis media".
** Includes 1073 non-Aboriginal children.

Table 2 is by no means an exhaustive review of the prevalence of CSOM although it does illustrate some important points in estimating the global burden of disease based on occasional surveys. First, the terms for middle ear disease overlap and the relationships among them are not very clear. "Chronic otitis media" might have included all types of otitis media that fail to resolve after an acute episode such as persistent or recurrent middle ear effusion, perforations that are dry and those that have resulted from accidental or surgical trauma or pressure changes. In the first of two Kenyan surveys and in the Angolan survey, chronic otitis media was more common than otorrhoea, suggesting that indeed the definition of chronic otitis media included non-draining ears. The second larger Kenyan survey reported that perforation was more frequent than chronic otitis media, suggesting that not all perforations were considered infectious in etiology.

"Perforation" might have been either dry and uninfected or discharging due to a cold or a persistent mastoid infection. Perforation and chronic otitis media may have been used interchangeably by the authors since all of the studies reported prevalence rates for either one but not both

"Otorrhoea" might have been due to external otitis, acute otitis media or CSOM. Otorrhoea rates were lower than perforation rates because the former is a subset of the latter, that is, most of the wet ears were due to draining perforations although not all perforations were wet.

Figure 1. Relationship of different definitions to CSOM



I – Chronic otitis media
A – Chronic middle ear effusion
D – CSOM

II – Perforation
B – Traumatic perforation
E – External otitis

III – Otorrhoea
C – Dry perforation

Thus, none of the terms correspond to CSOM alone. CSOM might have accounted for most cases of otorrhoea although not all perforations were due to CSOM. All three terms tended to overestimate the prevalence of CSOM in varying degrees but the magnitude of the bias is impossible to measure. Fig. 1 summarizes the possible relationships among the terms used by surveys and CSOM.

Second, the surveys differed in terms of the year they were done, choice of subjects, sampling methods, and survey coverage. Schoolchildren were examined in most of the surveys, particularly those involving South Pacific minorities and American Indians. In this respect, lumping together the very young, who were at the highest risk for otitis media, with older children, could have produced age-related biases. In contrast, some of the largest surveys, such as those in Tanzania, China, United Kingdom, Denmark and Finland, included all age groups. For example, the South Korean survey sampled the entire population in all age groups. The Chinese survey, while nationwide, covered only elderly people and represented only 1.5% of the entire Chinese population.

The Saudi Arabian study was a school-based survey that covered the entire city of Riyadh using a three-stage random sampling method. The Gambian survey was done in different schools throughout the country but did not sample randomly.

The Republic of Korea survey rates tended to decrease over time. The surveys with wider coverage tended to report lower prevalence rates than the majority that covered communities only. For example, in contrast to the community-based surveys in several African countries, the nationwide survey in Gambia reported the lowest prevalence of chronic otitis media among schoolchildren. The majority of the surveys did not specify the method of sampling or sample size calculation. None of the prevalence estimates was associated with confidence intervals.

Regional CSOM prevalence estimates

Because of considerable heterogeneity in survey methods, the country prevalence rates could not be systematically combined into a regional point estimate. Instead, a range of prevalence estimates was constructed for each region. Where several surveys have been done, and the range of prevalence rates is markedly wide, such as in Africa, South-East Asia and Western Pacific, the outlying values were dropped. Thus, the 14% prevalence rate from the Tanzanian survey among ENT patients, which was large but understandably high, was dropped. The very low Chinese prevalence rate (0.3%) from a nationwide survey of elderly people were excluded. It is probable that the prevalence of CSOM among Chinese children would be similar to those of other Asians with Chinese descent – about 4%.

The prevalences of chronic otitis media in the African countries are markedly similar to each other, ranging from 0.4% to 4.2%, partly because the subjects were all schoolchildren. Perforation rates ranged from 0.4% to 2.8%, and otorrhoea rates ranged from 0.4% to 3.6%. Thus the prevalence of CSOM in Sub-Saharan Africa ranges from 0.4% to 4.2% regardless of definition. The prevalence of chronic otitis media obtained by the two largest surveys (Kenya and Gambia) ranged from 0.6% to 1.1% and was very similar to the prevalence of otorrhoea in South Africa, Nigeria and Kenya.

Among the South-East Asian countries, prevalence rates in Thailand ranged from 0.9 to 4.7% while the Indian prevalence of 7.8% is high. This is a recent estimate from a school survey in Tamil Nadu and is lower than previous estimates that ranged from 16% to 34%.

Among Western Pacific countries, the prevalence rates clustered at the low end (2.5–4.2%) for Vietnam, Republic of Korea and Malaysia, and tended to be higher among the racially different Southern Pacific group of countries where high perforation rates ranged from 2.2–8.3% among Guamanians to 10.6% among Belau children. Australian whites had high rates (3–7%).

Australian Aborigines had the highest prevalence of perforation (28–43%) among all populations surveyed. A CSOM prevalence of 4% was deemed representative of most Asians, but not of Micronesians and Aborigines who must be considered as special high-risk groups. Among the other ethnic groups, American Indians had low rates but natives of Alaska and Greenland had rates ranging from 2% to nearly 10%.

The Saudi Arabian prevalence rate (1.5%) was taken as the Eastern Mediterranean regional estimate since this survey was large and subjects were systematically selected.

The CSOM prevalence of 1.5% among children in a Brazilian slum area was considered representative of South and Central America. The prevalence in North America was much lower and correlates well with the surveys in developed countries that yielded very low prevalence rates. A prevalence of 0.4% was considered representative of Europe.

Although the surveys were done among children, the prevalence of CSOM can be applied to the entire country because 1) CSOM persists up to early and middle adulthood, and 2) most developing countries have predominantly young populations in whom CSOM is most prevalent. Thus, the regional CSOM prevalence rates can be considered to apply roughly to the entire regional population. The number of persons with CSOM can be obtained by multiplying the regional prevalence rates with the population of each region. In this way, it can be shown that the global burden of CSOM is borne by India, China, Asia and other Pacific Islands, Sub-Saharan Africa, and the ethnic groups in Australia and North America.

Table 3. Global distribution of CSOM, by region (using low prevalence rates)

Region	Population	Regional prevalence of CSOM	Population with CSOM (rounded to nearest 100 000)	% of global CSOM burden	95% CL	
					Lower	Upper
Africa	2 601 783 000	0.4	2 400 000	3.68	3.63	3.72
Eastern Mediterranean	473 644 000	0.2	900 000	1.45	1.42	1.48
South-East Asia	1 485 056 000	1.4	20 700 000	31.76	31.60	31.90
Western Pacific	1 651 154 000	2.3	38 000 000	58.01	57.82	58.19
Americas	802 811 000	0.2	1 600 000	2.45	2.42	2.49
Europe	870 128 000	0.2	1 700 000	2.66	2.62	2.70
TOTAL	5 884 576 000		65 500 000			

Table 4. Global distribution of CSOM, by region (using high prevalence rates)

Region	Population	Regional prevalence of CSOM	Population with CSOM (rounded to nearest 100 000)	% of global CSOM burden	95% CL	
					Upper	Lower
Africa	2 601 783 000	4.2	25 300 000	7.70	7.67	7.73
Eastern Mediterranean	473 644 000	1.5	7 100 000	2.16	2.15	2.18
South-East Asia	1 485 056 000	7.8	115 800 000	35.30	35.23	35.36
Western Pacific	1 651 154 000	10	165 100 000	50.31	50.24	50.39
Americas	802 811 000	1.2	9 600 000	2.94	2.92	2.95
Europe	870 128 000	0.6	5 200 000	1.59	1.58	1.60
TOTAL	5 884 576 000		328 200 000			

(Source: WHO Annual Report, 1999)

Fig. 2. Regional contributions to the global CSOM using low (column 1) and high (column 2) prevalence estimates.

Tables 3 and 4 and Fig. 2 show that across the range of possible prevalence estimates, the Western Pacific and South-east Asian regions would contribute about 85–90% of the global burden from CSOM, with India and China accounting for much of the burden, the former by its high CSOM prevalence rate and the latter by its sheer size.

Hearing impairment

Review of prevalence of CSOM-associated hearing impairment

CSOM typically produces a mild to moderate conductive hearing loss (83). Because the eardrum is perforated and the middle ear ossicular chain may be disrupted by osteomyelitic erosion, sound vibrations enter the middle ear through the perforation and strike the oval and round windows. Theoretically and provided the cochlea is intact, the hearing loss produced is about 30 dB but may reach a maximum of 60 dB. Higher levels of hearing loss may result if the infectious process involves the cochlea or nerve (e.g. acute labyrinthitis, meningitis, etc.) or if patients are also exposed to potentially ototoxic drugs. How does this compare with actual field audiometric results? What proportion of CSOM patients have hearing impairment and how severe is it?

According to the included surveys, high proportions of children with otitis media have hearing impairment. Among 3772 Tanzanian patients, the majority of those with otitis media had 40–60 dB hearing thresholds. Table 5 shows the frequency of hearing impairment among CSOM cases and the frequency of CSOM as a cause of hearing impairment. The data were obtained from the series of surveys among children in Africa (13), India (83), and Sierra Leone (151), and among the general population in Thailand (7).

Table 5. Frequency of hearing impairment from CSOM in different study settings

Setting	Proportion of CSOM cases with hearing impairment	Proportion of cases of hearing impairment due to CSOM
Luanda, Angola (slum area)	66%	9.8% (12)
Angola (refugee camp)	52%	3.3% (15)
Tanzania (urban and rural district)	64.7%	3.6%
Tanzania (354 deaf children)		8.8% (117)
Luanda, Angola and Tanzania combined	63%	8.7%
Kenya	63% (76)	
Greenland (167 children)		14.5% (76)
Bauru, Brazil (urban poor and orphanage)	100%	13.7%
India	77%	
Sierra Leone (2015 rural children)		26.4% (151)
Thailand (6046 people from 6 regions)		52.2% (7)
Burma (90 000 schoolchildren)		80% (183)
Saudi Arabia (6421 schoolchildren)		19% (8)

Among African children with hearing loss from CSOM, 86% were mild (26–40 dB); the rest had moderate loss. Among Indian children with hearing loss from CSOM, 94% had moderate loss and the rest, severe. Among Sierra Leonean children, 86% of those with CSOM had hearing thresholds in the range 26–60 dB, while 8.7% had hearing thresholds higher than 60 dB.

Otitis media accounted for 91% of Vellore children (in India) and 66% of Saudi Arabian children with hearing loss. Minja (117) reported that, in 354 Tanzanian schoolchildren, otitis media accounted for 8.8% of all causes of hearing loss.

Regional hearing impairment prevalence estimates

Regional estimates of hearing impairment can be obtained with a method used by the WHO for estimating the burden of disease from blindness (163). What is the contribution of CSOM to the global burden of hearing impairment? A population-based survey in Swaziland in 1987 estimated that 30% or more of hearing impaired people would have CSOM (cited in 186). Based on the results of the surveys included in Table 5, CSOM accounts for 3% to 80% of the burden of hearing impairment.

Table 6. Regional burden of CSOM and hearing impairment from CSOM, 1990

Region	Population with CSOM	Regional burden of hearing impairment from CSOM (50% of CSOM population)
Africa	25 300 000	12 800 000
Eastern Mediterranean	7 100 000	3 500 000
South-East Asia	115 800 000	57 900 000
Western Pacific	165 100 000	82 500 000
Americas	9 600 000	4 800 000
Europe	5 200 000	2 600 000
TOTAL	328 200 000	164 100 000

Thus, about 164 million cases of hearing impairment may be due to CSOM and 90% of these would be in the developing countries (Table 6).

How much CSOM contributes to the global burden of hearing impairment is difficult to determine because of unreliable global estimates of hearing impairment. This tends to give a false impression that the problem does not exist. For example, the WHO reports significantly omit hearing impairment in its global burden of disease estimates for 1990 (126) and 1999, assigning 12 million DALYs for sense organ disorders based solely on cataracts and glaucoma (187). Deafness and hearing impairment do not have the same meanings (P. Alberti, in Forum Interview, 60), although the WHO, through its Prevention of Deafness and Hearing Impairment (PDH) Programme, has prepared performance-based grades of hearing impairment (65). Based on an estimate of 28 million hearing impaired people in the USA alone, and since the great majority of hearing impaired people are in developing countries, 200 million seems a more realistic global estimate (Kapur, in Forum Interview, 60) (74,183). This means that CSOM may contribute more than half to the global burden of hearing impairment, and eliminating it can potentially reduce the global burden by four-fifths.

Deaths

Review of CSOM-related mortality rates

In 1990, about 28 000 deaths all over the world and largely among developing countries were due to otitis media (82,125). Mortality and disabilities due to otitis media are primarily related to the complications of CSOM (18), particularly brain abscess (34). Population-based estimates in developing countries range from 0.24% in Thailand to 1.8% in Africa. In South Korea, 10.4% of CSOM had complications (128).

Cholesteatoma was found in over 60% of ears that had persistent otorrhoea for five years or more in Zaire (107), in 40% of children and 26% of adult cases in South Korea (128), in 0% among Navajo children (127), in 0.08% in Saudi Arabian children (123), and in 6.6 per 100,000 Greenland children (79).

Causes of CSOM-related deaths

The frequency of life-threatening complications from CSOM has been dramatically reduced by more than 10-fold with the introduction of sulfonamides in the 1930s and penicillin in the 1940s (18,91). In several case series, mortality rates from complications dropped precipitously from 76% in 1934 to 10% in 1963–82, and from 36% in 1939–49 to 0% in 1961–71. Non-randomized clinical trials in the 1940s and 1950s have also demonstrated reductions in clinical mastoiditis from 32% to 6% in sulfonamide-treated patients and from 8% to 1% in penicillin-treated patients (18). Mastoidectomy rates had also fallen from 20% in 1938 to 2.5% in 1948 (157).

In the developing world, however, mastoiditis and other complications are still the most common cause of death from CSOM. In Zaire, most deaths attributed to otitis media were due to serious complications arising from neglected draining ears (107). In Tanzania, 6% of cases of CSOM seen between 1978 and 1980 had complications, the most frequent of which was mastoid abscess. In an 8-year retrospective study of 17 444 patients with CSOM in an otolaryngology department in Thailand, suppurative complications were identified in 0.69%; 0.45% were extracranial complications, and 0.24% were intracranial (86); 40% of these patients had otorrhoea for less than 5 years. The most common extracranial complications were subperiosteal abscess and labyrinthine fistula; facial weakness, post-auricular swelling and otalgia were the most frequent symptoms and signs. Among these cases, 14.3% developed permanent facial paralysis or profound deafness. Meningitis was the most common intracranial complication, usually presenting with fever, headache, and meningeal signs. Among patients with intracranial complications, 18.6% died and 27.9% had permanent facial paralysis, profound deafness, diplopia, epilepsy or hemiparesis.

DALYs

Review of global burden of disease from otitis media

The 1993 World Development Report (185) estimated that about 5.12 million disability-adjusted life-years (DALYs) were lost from otitis media, 91% of which comes from the developing world. This was later scaled down in 1996 to 2.163 million DALYs (124), 94% of which still comes from the developing world. Table 7 shows that India and Sub-Saharan Africa (SSA) account for most deaths and years of life lost and DALYs from otitis media.

Table 7. Deaths, years of life lost (YLL), years lived with disability (YLD), and DALYs from otitis media, by region

Region (WHO)	Region (World Bank)	Deaths (thousands)	YLL (thousands)	YLD (thousands)	DALYS (thousands)
Africa	SSA	7	230	168	398
Eastern Mediterranean	MEC	3	117	153	270
South-East Asia	India	12	395	233	629
and Western Pacific	China	2	112	226	308
	OAI	3	108	190	298
Americas and Europe	EME	0	5	79	84
	LAC	0	8	120	128
	FSE	0	7	41	48
	World	28	952	1 211	2 163

SSA – Sub-Saharan Africa; MEC – Middle Eastern Crescent; OAI – Other Asian Islands; EME – Established Market Economies; LAC – Latin America and Caribbean; FSE – Former Socialist Economies.

Table 7 makes no distinction between acute and chronic otitis media. But since both death and long-term deafness are more common with CSOM than with acute otitis media, most of the years of life lost and years lived with disability in developing countries are due to chronic, not acute, ear infections. On the other hand, otitis media with effusion (OME) has increased over the past years. This has been reported most often in the developed world, where large cohorts in Europe and the USA have been subjected to regular and accurate diagnostic examinations (e.g. otomicroscopy and impedance audiometry) with near complete follow-ups. Given the already recognized differences in racial predisposition to middle ear disease, such an increase in incidence of OME is difficult to extrapolate to the developing world where resources for large cohort studies are limited.

WHO regional prevalence rates closely parallel the DALY counts. These data can be correlated with the estimated prevalence rates by WHO region. South-East Asia and the Western Pacific regions – where India, China and the other Asian islands are grouped by WHO – have both the highest prevalence of CSOM and the highest number of deaths and DALYs from otitis media. Otitis media cases in these two regions account for 61% of total deaths and 57% of total DALYs. Africa ranks second in terms of prevalence rates, deaths and DALYs. It contributes 25% of total deaths and 18% of the world's DALYs from otitis media.

Some 14% of deaths from otitis media come from Middle Eastern countries; no deaths are found in the Americas. The Americas and the Middle Eastern countries contribute equally to the remaining 25% of world DALYs.

Chapter Two
Diagnosis of CSOM

Diagnosis by history-taking

History-taking should be carried out to elicit the symptoms of ear pain, ear discharge, ear tugging or crying when the ear is touched, all of which suggest an ear problem. A history of previous ear discharge, especially when accompanied by episodes of colds, sore throat, cough or some other symptom of upper respiratory infection, should raise the suspicion of CSOM. A history of vigorous ear cleaning, itching or swimming that could traumatize the external ear canal suggests acute otitis externa (AOE), and not usually CSOM. A history of ear pain suggests AOE or AOM, not usually CSOM (24). In the case of AOM, the ear is only painful until the eardrum perforates, relieving the pressure. Thus, if the main symptom is painless otorrhoea, the duration of otorrhoea will help distinguish AOM from CSOM.

Reliable history-taking depends on good recall on the part of the patient or carer, an infrequent trait since neither parents nor teachers of children with otitis media have been shown to reliably estimate the number of otitis media episodes, the degree of hearing loss, or the possible impact of the condition (6). In developing countries, otorrhoea is often seen as a "normal" part of childhood. In Malaysia, 42% of children with CSOM did not give a previous history of ear discharge (52). In South Africa, none of those with CSOM actually presented with ear complaints (70).

The exact duration of otorrhoea that distinguishes CSOM from AOM is controversial, but this is only crucial in the absence of actual visualization of the eardrum. The size of the perforation, character of discharge, and the appearance of the middle ear mucosa on otoscopy can confirm the presence of CSOM more than patient anamnesis.

In using the IMCI algorithm in Kenya, the physician elicited a median duration of otorrhoea of 4 days (range, 1 to 240 days), but this was apparently not used in classifying patients as AOM or CSOM.

Diagnosis by otoscopy

The diagnosis of CSOM rests on the verification of a discharging tympanic perforation. This is only possible by removing any obstructing wax, ear discharge, debris or masses in the external auditory canal and visualizing the whole expanse of the eardrum and, if possible, the middle ear through the perforation. Such an examination requires adequate illumination through a head mirror, head light, otoscope or otomicroscope, suction apparatus and small instruments.

It also requires considerable skill and patience particularly when examining the ears of struggling children. A network of primary care doctors representing nine countries admitted a disconcerting 58% level of diagnostic uncertainty when diagnosing acute otitis media in patients aged 0–12 months. This rose to 66% for children aged 13–30 months and 73% for children older than 30 months (62). This would probably be true for CSOM also, given the obstructing material that would cover the tympanic membrane. In Kenya, the physician could visualize both tympanic membranes in only 84% of the children examined (138).

Not all draining ears are CSOM. Acute otitis externa and acute otitis media can produce both ear pain and ear discharge. However, tragal pain is found in otitis externa, mastoid pain in otitis media. The discharge in otitis externa is less profuse and foul-smelling and there is no mucus, as can be tested with a cotton mop by the tendency to form mucus threads. Fever is also higher in otitis media than in otitis externa (24). CSOM produces painless mucoid otorrhoea without fever, unless accompanied by otitis externa or complicated by an extracranial or intracranial infection.

Can CSOM be diagnosed even without otoscopy? Field testing of the WHO algorithm for the Integrated Management of Childhood Illness (IMCI) showed that, in most countries, the sensitivities of ear discharge in diagnosing "otitis" ranged from 60% to 95%. In Kenya, the sensitivity and specificity of health workers in detecting otorrhoea was 97% and 95%, respectively, compared with the physician (138). This led to highly accurate classification of patients with "chronic ear infection".

Specificities in most countries have a higher range – from 85% to 95%. In Gondar, Ethiopia, the sensitivity and specificity of health workers in detecting otorrhoea was 66% and 95%, respectively (154). Their sensitivity and specificity in classifying patients as "chronic ear infection" was 56% and 85%, respectively.

The wider range of sensitivity compared with specificity was probably due to varying prevalences of otitis media and raises the concern that, in places where CSOM is not frequently seen, the algorithm would miss patients with minimal ear discharge. This is highly undesirable because it not only underestimates the prevalence of disability from CSOM but also delays treatment until the disease is medically irremediable. A more sensitive way of determining otorrhoea, such as swabbing the ear canal with a cotton pledget or using a penlight to illuminate the ear canal better, is needed in the primary health care setting.

On the other hand, except for Kenya, the generally high specificity would mean that CSOM could be correctly diagnosed if otorrhoea were indeed present even when the eardrum was not seen. This makes the algorithm highly capable of selecting patients who truly have CSOM for treatment, while minimizing the risk of false positivity that may overtreat patients or overload the referral system.

Still it is possible to misdiagnose a patient with otorrhoea as a case of acute otitis externa or otitis media, but what would be its impact? If misdiagnosing CSOM as acute otitis externa would lead to ear wicking and other topical treatments, these would also be useful for uncomplicated CSOM. If misdiagnosing CSOM as acute otitis media would lead to systemic antibiotic treatment as well as ear wicking, they would be less beneficial than topical antibiotic treatment alone. The consequence would be decreased efficiency (because of increased cost of medication and lower effectiveness) and exposure to systemic adverse reactions.

But even without otoscopy it can be assumed that any ear that continues to discharge for more than 2–3 months is already CSOM, or has a high risk of becoming CSOM since both AOM and otitis externa are self-limiting. AOM usually resolves within days in developed countries, or within two to three months regardless of whether the drum perforates or whether treatment is given (148,161,162,173). In the presence of co-morbidity like a protracted respiratory infection or malnutrition, the likelihood of non-resolution is higher. The question is whether one should wait for otorrhoea to persist for 2 to 3 months before treating a newly discharging ear as a case of CSOM when it is certain that once the diagnosis of CSOM is made, the likelihood of resolution with medical treatment is low. The need for pre-emptive action against CSOM, even when the otological diagnosis is not exact, has also been recognized by the Gambian Hearing Health Project: patients with draining ears were immediately given kits containing topical antiseptics and rubber bulbs for ear irrigation (75).

Continuing the antibiotic therapy for a case of acute otitis media that fails to resolve immediately can thus be considered the first important step in preventing CSOM and is justified by two important research findings:

1. The observation that antibiotic therapy decreased the incidence of acute mastoiditis complicating acute otitis media (19,148), similar to the decrease in suppurative complications among antibiotic-treated patients with streptococcal pharyngitis; and
2. A meta-analysis that showed the short-term benefits of prolonged antibiotics on patients with recurrent otitis media.

Diagnosing patients as CSOM cases even earlier than the 2–3-month deadline for acute otitis media to resolve is, therefore, probably justified if it leads to a pre-emptive treatment of the infection, unless otoscopic findings indicate imminent resolution. Again the availability of cost-effective antibiotics with relatively low likelihood of adverse reactions would justify such an empiric policy.

The diagnostic value of bacterial cultures

In places where bacterial cultures are available, can they be used to aid in diagnosing CSOM? Bacterial cultures may not be needed to establish the diagnosis of CSOM since exhaustive studies have established that 90–100% of chronic draining ears yield two or more isolates consisting of both aerobic and anaerobic bacteria (24,93,141,150,153). Also, treatment may eradicate middle ear bacteria but this does not guarantee non-recurrence of otorrhoea or complete resolution of the CSOM. Leiberman et al. (99) reported recovering *Pseudomonas aeruginosa* from draining ears in the pre-treatment and in the recurrent stage. Some would argue that perforated drums might develop discharge from time to time even without the presence of bacteria and that this does not constitute CSOM which must be treated. In practice, however, patients with draining ears do expect some treatment regardless of culture results. Since topical treatment is often effective and seldom harmful, most experts would start with a wide-spectrum antibiotic on an empiric basis and make a request for cultures if drug resistance is suspected (150,152).

Chapter Three
Management of CSOM

The two principal aims of management are the eradication of infection and the closure of the tympanic perforation. Both are important. While the abiding presence of pathologic bacteria within the middle ear and mastoid cavities accounts for the mortality and severe morbidity associated with CSOM, the persistent tympanic perforation represents unrelieved hearing loss and the constant threat of microbial invasion of the middle ear.

Features of CSOM that can be managed medically

The distinction between some forms of CSOM that are better managed surgically and other types should be made early on in the management of the disease. This will avoid delay in operating on those patients whose infections are medically intractable from the outset.

Generally, infection that involves the hidden upper recesses (attic) of the middle ear and the mastoid antrum (attico-antral disease) is usually too deep within the ear to be reached by antibiotics. A cholesteatoma, a nest of squamous keratinizing epithelium within the middle ear cleft that destroys bone and permits spread of infection is a surgical disease. CSOM associated with diffuse mucosal disease is often medically intractable because of the destructive osteitis and granulations involving the mastoid bowl and middle ear. These conditions are often associated with a purulent foul-smelling discharge that fails to resolve with the usual course of antibiotics.

In addition, recognition of the suppurative complications within and/or outside the cranial cavity should also immediately exclude such patients from medical management and should call for immediate mastoidectomy. Such complications include subperiosteal abscesses, facial nerve paralysis, lateral sinus thrombophlebitis, suppurative labyrinthitis, brain abscess, meningitis and otitic hydrocephalus.

Generally speaking, patients with CSOM that can be managed by conservative medical treatment usually experience mucoid, foul- or non-foul smelling, occasionally profuse otorrhoea oozing through a central tympanic perforation involving neither the drum margin nor its posterior region. Among such patients, medical treatment can be aimed at control of infection and elimination of ear discharge as short-term goals and eventual healing of the tympanic perforation and improvement of hearing as ultimate goals.

Literature review

A recently published systematic review of randomized controlled trials (RCTs) in the Cochrane Library attempts to summarize the results of best available evidence on these issues (1). The 24 RCTs included in this review were retrieved from MEDLINE and manual searches of the Archives of Otolaryngology – Head and Neck Surgery and Clinical Otolaryngology.

In addition, 18 more RCTs were retrieved by the staff of the ENT Disorders Review Group based in Oxford, England, using the the terms "chronic otitis media" and the standard search strategy used by the Cochrane Collaboration for RCTs.

The methodologic qualities of these RCTs varied and were generally low, often suffering from ambiguous case definitions and subject inclusions, lack of concealment of randomization sequence, lack of blinding, incomplete patient follow-up, and small sample sizes. Clinical definitions of CSOM varied but the majority of trials included positive bacterial cultures of the middle ear in their patient inclusion criteria. Otoscopic findings of eardrum perforation with active discharge were the common definition of CSOM but studies differed with regard to duration of otorrhoea, status of the middle ear and presence of middle ear bacteria. The most commonly measured outcome was disappearance of discharge after treatment, but post-treatment observations were too short to demonstrate lasting benefits and the studies that attempted to do this did not find significant differences in hearing status or closure of perforation between treatments.

Aural toilet

Aural toilet is no better than no treatment

There is no consensus among general and specialist physicians with regard to the medical management of CSOM. However, there is general agreement that aural toilet must be part of the standard medical treatment for CSOM. Cleaning the ear of mucoid discharge could reduce, even if temporarily, the quantity of infected material from the middle ear and could facilitate middle ear penetration of topical antimicrobials (105).

From the Cochrane review, aural toilet alone was not significantly better in resolving otorrhoea (OR = 0.63, 95%CL = 0.36, 1.12) and in healing perforations (OR = 1.04, 95%CL = 0.46, 2.38) than no treatment. This was based on two field trials among children in the Solomon Islands (50) and Kenya (155). Further studies are therefore needed to demonstrate the benefit of aural toilet alone. As discussed in the next section on Antimicrobial Treatment, aural toilet must be combined with antibiotics or antiseptics to be effective.

Practical implications

Aural toilet is best performed in the clinics by means of small suction tips, forceps and curettes (95) to remove small mucosal granulations from the middle ear. This would ordinarily require skilled otologists working with good illumination and magnification.

In addition, aural toilet could be continued outside the clinic by means of irrigating the ear with cleaning solutions and/or dry mopping the ear with cotton wool wisps on orange sticks four times per day. The patients themselves, their parents, schoolmates or teachers could perform this.

Brobby did not recommend syringing the ear as it might cause irritation of the vestibular apparatus or infection of the labyrinth. Nonetheless, most authors agree on the benefits of mechanically swishing cleansing solutions inside the ear (135,152). This seems to be the principal action of wet irrigation. The type of irrigating solution, although a secondary issue, might include the following:

- Half-strength vinegar, using one-half cup of white vinegar and one half-cup water (152).
- Half-strength saline or rubbing alcohol, using one-half cup of alcohol and one half-cup water (97).
- Hydrogen peroxide (95).
- Half-strength povidone-iodine (152).
- Saline solution (150).

Irrigating solutions must be warmed to near body temperature so as not to induce vertigo. They can be instilled into the middle ear by means of medicine droppers or bulb syringes. Alternately compressing and releasing the rubber bulbs to instil and suck back the solution could mechanically dislodge mucus and debris from the middle ear. This is repeated until the return is clear. The patient may perform a

Valsalva manoeuvre to further express mucus from the Eustachian tube into the middle ear for removal.

The patient then mops the ear dry with a cotton-tipped applicator. Since commercially available cotton buds tend to be too large for children's ears, patients must be taught how to fashion suitably sized pledgets by winding tufts of cotton to the tips of wire or wooden applicators. The tips of tightly wound pieces of cloth or napkins may also be inserted inside ear canals to wipe off discharge.

The entire procedure is done two to three times daily until discharge disappears (150). The entry of water or soap into the ear, particularly during bathing, is avoided by plugging the ear with rubber or cotton wool covered with vaseline (97). This also prevents soiling and irritating the skin surrounding the ear canal with infected discharge (159).

Antimicrobial treatments

From the Cochrane review, aural toilet combined with antimicrobial treatment is more effective than aural toilet alone (OR = 0.31, 95%CL = 0.23, 0.43) (26,49,57,138,147,153). Except for one study (50), which combined topical framycetin-gramicidin and oral clindamycin, the rest of the RCTs consistently favoured antimicrobial treatments – oral amoxycillin, metronidazole, and lincomycin; topical gentamicin/ hydrocortisone, Sofradex (framycetin, gramicidin and dexamethasone); intravenous mezlocillin, ceftazidime, and intramuscular gentamicin were used.

However, the choice of antimicrobial treatment to be combined with aural toilet is a highly contentious issue. A 1985 survey of paediatricians in Dallas, Texas (USA), found that 79% would prescribe topical antibiotics and 100% would use oral antibiotics as well. A consensus of management formed by 141 physicians with expertise and interest in middle ear infections yielded the following recommended treatment: suction out and culture the discharge, prescribe oral antibiotics, and adjust according to sensitivity results. Ludman (105) and Nelson (127) advocated similar approaches and cited potential ototoxic effects as a major disadvantage of topical antibiotics. On the other hand, most otolaryngologists recommend topical antibiotic therapy and point out the poor penetration by most antibiotics into a devascularized middle ear mucosa marked with subepithelial scarring and thickening (85). An initial trial of topical antibiotics is recommended and oral antibiotics may be added if a susceptible organism is cultured.

To answer the question of what antimicrobials should be combined with aural toilet, the randomized controlled trials included in the Cochrane review of Acuin, Smith & Mackenzie (1) were re-analysed. Thus, a separate meta-analysis was made for the purpose of this report.

Oral antibiotics

Oral antibiotics are better than aural toilet alone

A trial comparing various oral antibiotics with aural toilet alone (149) reported a higher otorrhoea resolution rate in the antibiotic treated group (OR = 0.35, 95%CL = 0.14, 0.87). Another trial comparing oral clindamycin with aural toilet alone found otorrhoea resolution rates of 93% and 29%, respectively (37).

Some oral antibiotics are as good as others

Similar rates of otorrhoea resolution were found between cefotiam and amoxycillin-clavulanic acid (61% and 65%, respectively) by Cannoni et al. (30) and between cefotiam and cefuroxime (67.2% and 69.8%, respectively) by Dellamonica et al (44). In the Cannoni trial, adverse effects were more common among the amoxycillin-clavulanic acid-treated group (36%) than in the cefotiam-treated group (14%). In the Dellamonica trial, the rates were 15% and 11.5% for the cefuroxime-treated and the cefotiam-treated groups, respectively.

Topical antibiotics

Topical antibiotics are better than aural toilet alone

The addition of topical antibiotics to aural toilet was associated with a 57% rate of otorrhoea resolution, compared to 27% with aural toilet alone (27,50,61,88,139) (OR = 0.31, 95%CL = 0.19, 0.49). The topical antibiotics used were framycetin, gramicidin, ciprofloxacin, tobramycin, gentamicin and chloramphenicol. Podoshin et al. (142) also showed that topical ciprofloxacin or tobramycin was more effective than placebo (clinical response rates were 78.9%, 72.2% and 41.2%, respectively)

Topical antibiotics are better than systemic antibiotics

The Cochrane review found that topical antibiotics were more effective than systemic antibiotics in resolving otorrhoea and eradicating middle ear bacteria (OR = 0.46, 95%CL = 0.30, 0.68). Six studies (27,54,55,136,145,189) used gentamicin, chloramphenicol, ofloxacin, and ciprofloxacin as topical antibiotics; hydrogen peroxide, and boric acid with iodine powder as topical antiseptics; and cephalexin, flucloxacillin, cloxacillin, amoxycillin, coamoxiclav, erythromycin, metronidazole, piperacillin, ciprofloxacin, azactam, trimethoprim-sulfa, ofloxacin, and intramuscular gentamicin as systemic antibiotics. An alternative analysis that excluded two less rigorous trials decreased the heterogeneity and further showed benefit in favour of topical treatment (OR = 0.19, 95%CL = 0.1, 0.32).

Similarly, one additional RCT (43) found that topical ciprofloxacin was better than oral ciprofloxacin (86% versus 60% in terms of clinical and bacteriological cure, respectively).

Topical quinolones are better than topical non-quinolones

The Cochrane review showed that among topical antibiotics, topical fluoroquinolones are more effective than other types of topical antibiotics. Five studies (55,61,103,165,171) found that topical ofloxacin or ciprofloxacin was more effective than intramuscular gentamicin, topical gentamicin, tobramycin or neomycin-polymyxin in resolving otorrhoea (OR = 0.36, 95%CL = 0.22, 0.59) and in eradicating bacteria (OR = 0.34, 95%CL = 0.20, 0.57).

Five additional RCTs (43,61,118,142,160) showed similar results. Fradis et al. (61) observed otorrhoea resolution rates of 47.4% and 55% for topical ciprofloxacin and topical tobramycin, respectively, and 66% bacterial eradication rates for both groups. Supiyaphun et al. (160) found that topical ofloxacin was more effective than topical chloramphenicol (with oral amoxycillin) in terms of resolution of ear discharge (76.9% and 37%, respectively), ear pain (79.2% and 53.3%, respectively), and middle ear inflammation (63.2% and 54.8%, respectively). Podoshin et al. (142) showed that topical ciprofloxacin was marginally better than topical tobramycin (78.9% and 72.2%, respectively). Miro (118) found that topical ciprofloxacin was more effective than topical polymyxin-neomycin-hydrocortisone in terms of clinical response (87% and 76%, respectively), but the bacterial eradication rates were the same (79% and 76%, respectively). De Miguel Martinez et al. (43) showed that resolution of otorrhoea was higher with topical ciprofloxacin (86–88%) than with topical polymyxin-neomycin (56%).

Combined topical and systemic antibiotics are no better than topical antibiotics alone

Should oral antibiotics be added to topical antibiotics? The Cochrane review showed that combined oral-topical antibiotics were no more effective than topical antibiotics alone; the rates of resolution of otorrhoea were 50% and 53%, respectively. The drugs compared were clindamycin with topical framycetin-gramicidin vs framycetin-gramicidin alone (50), oral and topical ciprofloxacin vs topical ciprofloxacinalone (54), and metronidazole with gentamicin vs gentamycin alone (140) (OR = 1.71; 95%CL = 0.88, 3.34). In terms of eradication of middle ear bacteria, oral and topical ciprofloxacin were slightly more effective than topical ciprofloxacin alone (15% vs 5%), but this was not statistically significant (54).

In two more recent RCTs, one (160) found that the clinical response rates were better with topical ciprofloxacin (range, 63.2–79.2%) than combined topical chloramphenicol and oral amoxycillin (range, 37–54.8%), while the other (43) showed the cure rates with topical ciprofloxacin and with combination oral and topical ciprofloxacin to be the same (88%).

Thus, although combination antibiotics are effective in resolving otorrhoea, adding oral antibiotics to topical antibiotics and aural toilet increases the cost without increasing the success rate. This confirms the difficulty of systemic drug penetration through the devascularized, fibrotic mucosa of the middle ear and mastoid. It also emphasizes the critical role of local treatment.

With regard to restoration of hearing, no RCT addressed this outcome. However, if we take closure of the perforation as a proxy measure for hearing improvement, combination oral and topical antibiotics were no better than no treatment in healing perforations (155) (OR = 0.95, 95%CL = 0.46, 1.96).

Practical implications

The effectiveness of topical treatment shown in this systematic review is corroborated by many case series on treatments for CSOM (26,29,38,64,69,89,115,133,144), as well as by expert opinions in many widely accepted textbooks in otolaryngology (39,47,110,116,135, 152). Powdered antibiotics and antiseptics are routinely recommended when there is good access to the middle ear cavity, such as in cases of subtotal tympanic perforations or draining mastoid cavities (85). Table 8 shows other topical antibiotics that have been directly instilled into ears with CSOM.

Table 8. Topical antibiotics for CSOM, as reported in the literature

1. Ophthalmic antibiotic drops containing buffered neutral solutions of gentamicin, tobramycin, sulfisoxazole, chloramphenicol, sulfacetamide, tetracycline, polymyxin B, trimethoprim, norfloxacin, ofloxacin, ciprofloxacin and erythromycin (85,97)
2. Various steroid drops such as hydrocortisone, fluocinolone and triamcinolone
3. Powdered sulfanilamide (84)
4. Powdered fungizone (97)
5. Powdered sulfathiazole.

The risk of ototoxicity is one stumbling block in the widespread use of topical antibiotics. But much of the evidence on ototoxicity consists of experimental introduction of putative agents into intact, normal middle ears or painted on the round window membranes of animals such as chinchillas, rats and baboons (56,121,122). Unlike that of animals, however, the round window membrane (the structure which drugs penetrate to gain access to the inner ear) of humans is more deeply set within bone. The human round window is protected by a “false” membrane, four times thicker in the normal state and possibly even thicker during inflammatory states (e.g. otitis media). Paparella et al. (134) found that decreased permeability of the round window membrane to horse radish peroxidase among cats with experimentally produced otitis media was due to three factors: thickening of the round window membrane by inflammatory cell infiltration of the subepithelial space, thick inflammatory exudate overlying the round window, and granulation tissues within the round window niche (81,134).

Documenting ototoxicity is also difficult because ototoxic drugs characteristically affect the very high frequencies – 4 kHz and higher (120,122). Standard audiometers all reach 8 kHz but screening audiometers stop at 4 kHz.

There have been several case reports of sensorineural hearing loss in humans following administration of ear drops (109,121,146,188); however, these case reports have not changed the clinical practice of most clinicians (109,121). Clinicians rarely see them and a recent survey showed that 80% were more concerned with the very real danger of sensorineural hearing loss from otitis media than with the theoretical possibility of ototoxicity from topical antibiotics (146). In two separate clinical trials, patients treated with topical gentamicin did not show significant post-treatment threshold shifts (26,69). A series of 286 adult patients with CSOM also showed that elevated bone conduction thresholds were unrelated to the disease process (28).

Still, topical antibiotics are not widely accepted in all countries. In the United Kingdom, for example, the Committee on Safety of Medicine, despite appeals by the British Academy of Otorhinolaryngology – Head and Neck Surgery (BAO-HNS), had recently ruled that aminoglycoside ear drops are “contraindicated when the patient has a perforation of the ear drum because of the risk of ototoxicity” (113).

The safety and effectiveness of topical quinolones in children have been well documented (48). Adverse reactions have been minor and as frequent as with other topical antibiotics. The concentrations of these drugs are highest in otorrhoea, the main route of exit from the ear, and lowest in the serum (130).

Parenteral antibiotics

Parenteral antibiotics are better than aural toilet alone

One trial (58) found that intravenous mezlocillin and ceftazidime were more effective than aural toilet alone in resolving otorrhoea and eradicating middle ear bacteria (100% and 8%, respectively). Another trial (100) found that more CSOM patients who were given IV ceftazidime prior to mastoidectomy had dry ears (93%) than those who did not (42%).

Similar to the comparisons among oral antibiotics, a trial comparing IV ceftazidime and IV aztreonam found the same otorrhoea resolution rates in 2 months

(87%) and similar mean "time to dry ear" (7.9 days and 8.4 days, respectively).

This result has been supported by Kenna et al. (92) in a case series of 36 children given intravenous anti-pseudomonal drugs for 7–14 days. Azlocillin was the most frequent drug given; other drugs are noted in Table 9; 89% of patients with CSOM experienced resolution of otorrhoea during hospitalization and only 4 out of the 32 children underwent mastoidectomy. However, 19% of the patients developed recurrence of otorrhoea in one year.

Leiberman et al. (99) administered IV mezlocillin or ceftazidime and observed 100% resolution of otorrhoea after treatment, but noted recurrence rates (after 12, 18 and 24 months) of 29%, 34% and 48%, respectively, with 80% of recurrent otorrhoea developing during the first 6 months after treatment.

Table 9. Parenteral antibiotics for CSOM (21,93)

1. Penicillins:	Carbenicillin, piperacillin, ticarcillin, mezlocillin, azlocillin, methicillin, nafcillin, oxacillin, ampicillin, penicillin G
2. Cephalosporins:	Cefuroxime, cefotaxime, cefoperazone, cefazolin, ceftazidime
3. Aminoglycosides:	Gentamicin, tobramycin, amikacin
4. Macrolides:	Clindamycin
5. Vancomycin	
6. Chloramphenicol	
7. Aztreonam	

Parenteral and oral antibiotics plus aural toilet are better than aural toilet alone

The combination of parenteral and oral antibiotics have been shown in a RCT by Rotimi (149) to be more effective than aural toilet alone (OR = 0.35; 95%CL = 0.14, 0.87). Rotimi combined oral clindamycin, metronidazole and lincomycin with intramuscular gentamicin.

Topical antiseptics

Topical antiseptics may be as effective as topical antibiotics

Topical antiseptics tended to be more effective than aural toilet alone in resolving otorrhoea in the trial by Eason et al. (50) (OR = 0.67, 95%CL = 0.2, 2.25). This promising result is corroborated by three trials that were included in the Cochrane review (27,35,50). Topical antiseptics were found to be just as effective as topical antibiotics; however, olfoxacin/ciprofloxacin produced high cure rates. The trial by Eason et al. (50) found boric acid to be slightly more effective than framycetin-gramicidin. Browning et al. (27) found that boric acid plus iodine powder was slightly more effective than topical chloramphenicol and various oral antibiotics (cloxacillin, flucloxacillin, cephalexin and amoxicillin). Clayton et al. (35) found gentamicin to be slightly more effective than alum acetate and gentamicin. The combined estimate of the three trials showed no difference in effectiveness between topical antibiotics and topical antiseptics in resolving otorrhoea (OR = 1.34, 95%CL = 0.64, 2.81), although it is possible that antibiotics will be more effective than antiseptics if the trials were larger. The combined sample size was still small and, judging from the width of the 95% confidence interval, had little power to detect small differences in effectiveness. More powerful topical antibiotics such as quinolones may also prove to be more effective than antiseptics.

The antimicrobial properties of topical antiseptics must be further elucidated by research, but clinical experience of their effectiveness abounds in the medical literature. Aside from boric acid and alum acetate which were used in the three RCTs mentioned above, other topical antiseptics that have been reported in the literature are shown in Table 10.

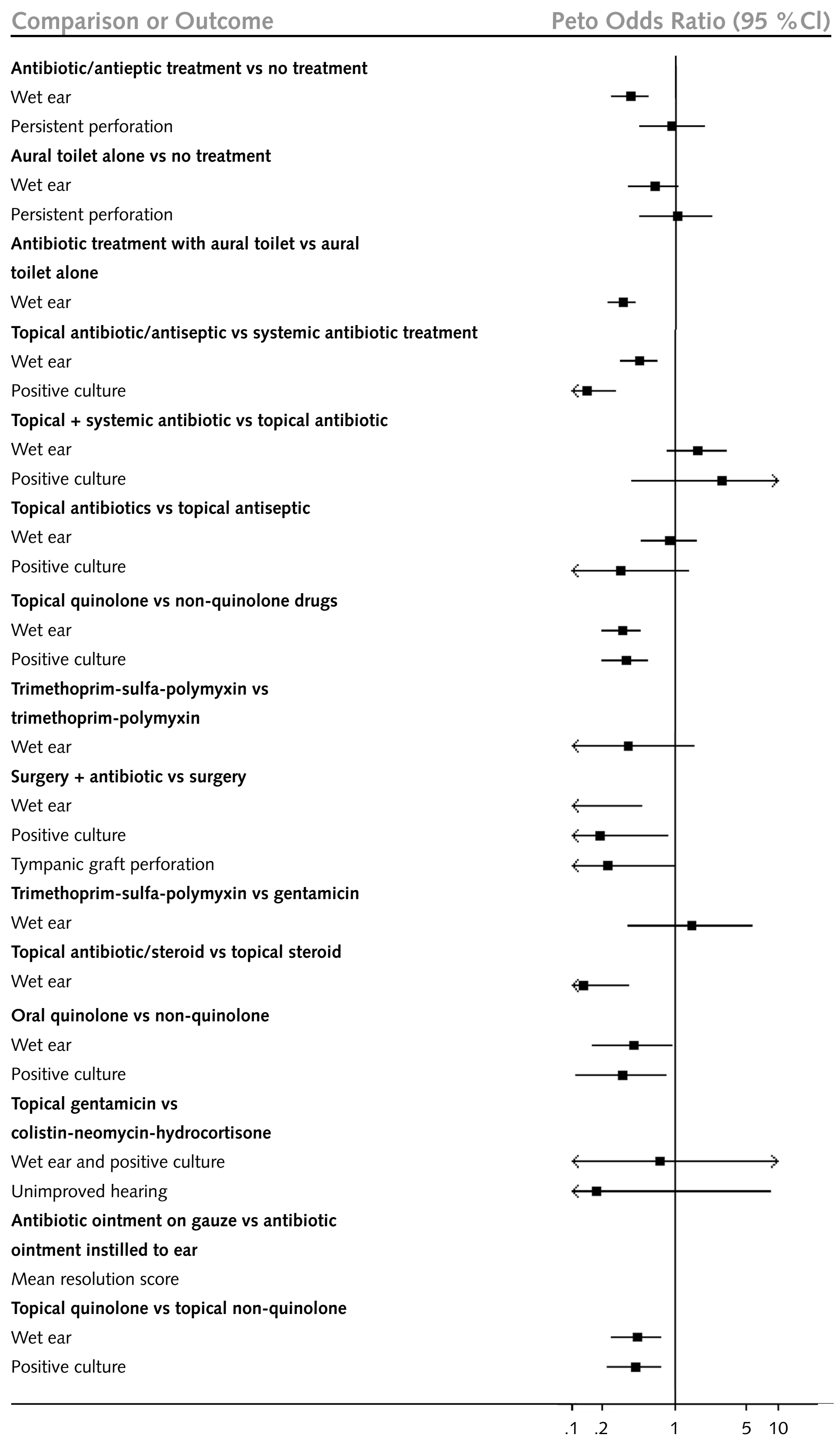
Table 10. Topical antiseptics, as reported in the literature

Boric acid (50)
Zinc peroxide powder (47)
Iodine powder (27)
Dilute acetic acid drops, such as Domeboro solution or Vosol (85)
Alum acetate or Burow's solution (38,107)
Spirit eardrops BPC containing industrial methylated spirit and water (24,110)

In addition, Wilde et al. (182) reported using TAC ointment, consisting of topical triamcinolone (0.1%), gramicidin (0.025%), neomycin (0.25%) and nystatin, to fill the entire middle ear cavity or to impregnate ribbon gauze which was packed into the ear. Mahoney used ear wicks impregnated with alum acetate in a mass treatment of draining ears in Zaire (107).

The physical properties of these topical antimicrobials may be just as important as their antimicrobial actions. Several authors (85,153,182) pointed out the importance of prolonged contact of the agent with the middle ear mucosa so that ointments, powders and suspensions are preferable to plain solutions. The local drying effect of antibiotic powder on weeping middle ear cavities is widely recognized and seems to be independent of any specific antimicrobial activity (95). However, care should be taken to completely cover all accessible middle ear mucosa with powder for adequate periods for the antiseptic powders to take effect. Boric acid may also be uncomfortable to the ear (84).

Fig. 3 Summary results of systematic review of treatments for CSOM



Cost-effectiveness analysis of different interventions for CSOM

The superiority of aural toilet with topical antibiotic treatment implies a change in the current management of CSOM. Ear wicking alone, as advocated by the WHO guidelines for the Integrated Management of Childhood Illness (67), is not sufficient. In cases where the nature of the otorrhoea is unclear or where antimicrobial treatment is not feasible, aural toilet alone would tend to reduce the odds of otorrhoea from 0.80 to 0.74 (or by 0.06). Even greater reductions in the odds of otorrhoea could be obtained by changing from aural toilet alone to aural toilet with antimicrobial treatment: the odds could then be lowered from 0.75 to 0.46 (or by 0.29).

The cost-effectiveness analysis comparing the different treatment options is shown in Table 11. The CSOM patient is assumed to be a child (aged 7 years and weighing 22 kg), who presents for the first time with an ear discharge but without any co-morbidity or surgical indication.

The drugs that were selected to represent each treatment option came from the clinical trials on which the effectiveness data are based. In cases where clinical trials used several drugs of the same type, a representative antibiotic was selected if other treatment options used the same antibiotic. For example, although six topical antibiotics were used by the three clinical trials that compared topical antibiotics plus aural toilet versus aural toilet alone, the representative antibiotic was polymyxin-neomycin – corresponding to framycetin-gramicidin (50). Of the two oral/topical antibiotic combinations used by Eason et al. (50) and Smith et al. (155), clindamycin/polymyxin-neomycin (50) was selected. This allowed direct comparison of costs between the topical antibiotic option and the oral/topical antibiotic option. The parenteral antibiotic was ceftazidime (58) and the oral/parenteral antibiotic combination was clindamycin/gentamicin (149).

The direct cost of each treatment option (in US$) is based on current retail prices (191) of the following drugs for two weeks of treatment:

· Topical antibiotic option: one bottle of neomycin-polymyxin-steroid otic drops = $2.50.

· Oral antibiotic option: clindamycin 75 mg/5 ml suspension, given 10 mg/kg/day or one teaspoon (5 ml) TID for 2 weeks; total amount: 4 (60 ml) bottles = $16.90.

· Oral/topical antibiotic option: clindamycin suspension for 2 weeks ($16.90) plus one bottle of neomycin-polymyxin-steroid otic drops ($2.50) = $19.40.

· Parenteral antibiotic option: ceftazidime 2 g/vial given at 30 mg/kg every 8 hours or 2 g daily for 14 days = $483.

· ‘Parenteral/oral antibiotic option: gentamicin 20 mg vial given at 2mg/kg every

8 hours or 120 mg daily for 14 days ($115.50) plus clindamycin suspension for 2 weeks ($16.90) = $132.40.

· Topical antiseptic: one bottle of boric acid powder suspension = $0.60.

· Aural toilet / ear wicking material for 2 weeks = $0.30.

A societal viewpoint was adopted for this economic analysis because the prevention, management and rehabilitation of patients with CSOM must necessarily involve the government sector. Since CSOM is more prevalent in developing countries where patients are less able to pay from their own pockets, financial support for such management must fall on the public sector. For government spending to be efficient, CSOM management must build on existing resources of the health care delivery system and must be integrated with current programmes at all levels of health care. The diagnosis and treatment of CSOM should be apportioned to each of these levels and horizontally integrated with what the health workers can do or are already doing.

Indirect costs, such as wages lost by parents or carers who accompany the child, were considered but not included because the number of outpatient visits (i.e. time away from work) was the same regardless of the treatment choice. The effectiveness data, expressed as the number of dry ears per 100 persons treated, came from the relative risks of the relevant clinical trials included in the meta-analysis.

Effectiveness data

Aural toilet alone

Two RCTs (50, 155) in the Cochrane systematic review (1) addressed this problem. Eason et al (50) observed that 50% of 26 ears of school children studied became dry with aural toilet alone. Smith et al (155) reported that a weighted mean proportion of 22% of 144 school children in the aural toilet group had dry ears. The review reported a pooled event rate of 26.5% for dry ears.

Antibiotic or antiseptic treatment vs. aural toilet alone

As was noted earlier, the pooled data from six RCTs in the systematic review showed the superiority of antimicrobial treatment over aural toilet alone. The pooled event rates for dry ears after treatment were 53.7% (278 / 518) for antimicrobial treatment versus 25% (69 / 276) for aural toilet alone (risk difference = 28.7%).

Topical antibiotics vs aural toilet alone

The trial by Browning et al (26) found that 48.4% (31 / 64) of ears receiving topical gentamicin and aural toilet versus 25.4% (15 / 59) of ears receiving topical placebo and aural toilet were dry after four weeks of treatment (risk difference = 23%).

Eason et al. found that 58% of 41 ears treated with topical framycetin-gramicidin-dexamethasone and aural toilet versus 50% of 19 ears treated with aural toilet alone became dry (risk difference = 8%). Picozzi et al (139) reported that 64.7% (11/17) of ears treated with topical gentamycin-hydrocortisone and self-mopping versus 21.4% (3/14) of ears treated with topical placebo and self-mopping became dry (risk difference = 43.3%).

Topical antiseptics vs aural toilet alone

64% of 32 ears treated with topical borate and aural toilet became dry compared with 50% of 26 ears treated with aural toilet alone (risk difference = 14%) (50).

Systemic antibiotics vs aural toilet alone

Rotimi et al (149) found that 50.4% (60 / 119) of subjects treated with oral clindamycin, metronidazole or lincomycin, plus intramuscular gentamicin and aural toilet had dry ears after six weeks compared with 23.8% (5 / 21) of subjects given aural toilet alone (risk difference = 26.6%). Fliss et al (58) reported that 100% of 21 subjects who were given intravenous mezlocillin or ceftazidime and daily suctioning were dry after 14 days compared with 8.3% (1/12) of subjects who received daily suctioning alone (risk difference = 91.7%).

Oral and topical antibiotics

Eason et al (50) reported that 43% of 40 ears treated with topical framycetin-gramicidin-dexamethasone, oral clindamycin and aural toilet became dry after six weeks of therapy compared with 50% of 26 ears treated with aural toilet alone (risk difference = -13%). On the other hand, Smith et al (155) found that a weighted mean proportion of 51% of 184 children treated with topical framycetin-gramicidin-dexamethasone, oral amoxicillin and aural toilet had dry ears at sixteen weeks of follow-up compared with 22% of 144 children treated with aural toilet alone (risk difference = 29%).

From the point of view of efficacy, parenteral antibiotics produce excellent resolution of otorrhoea. However, these are usually anti-pseudomonal drugs like ceftazidime and tend to be very expensive. Aminoglycosides such as gentamicin are less expensive but, as the trial by Rotimi et al (149) showed, are less effective even when combined with oral antibiotics.

The most efficient treatment option is aural toilet and topical antiseptics: US$2.14 would be spent for every dry ear compared with aural toilet alone. The least cost-effective option would be intravenous ceftazidime followed by intramuscular gentamicin with oral clindamycin.

Table 11. Cost-effectiveness analysis of alternative treatments to ear wicking

Treatment	Cost / 100 patients treated (a)	No. of dry ears / 100 patients treated (b)	Incremental analysis		
			Cost difference (c)	Additional no. of dry ears (d)	Cost-effectiveness ratio (e)
Aural toilet alone (base case)	30	26			
Topical antiseptic	60	64	30	14	2.14
Topical antibiotic	250	48	220	23	9.56
		58		8	27.5
		65		43	5.12
Oral and topical antibiotics	1940	51	1910	29	65.86
Parenteral antibiotic (ceftazidime)	48 300	100	48 270	92	524.67
Parenteral and oral antibiotics (clindamycin plus gentamycin)	13 240	50	13 210	27	489.26

(b) Single or pooled event rates in the treatment arms of randomized controlled trials included in a meta-analysis.
(c) Column a minus cost of aural toilet (US$ 30).
(d) Risk differences reported in meta-analyses or individual trials; percentages are converted to n / 100.
(e) Column c divided by column d.

Surgery

Mastoidectomy and/or tympanoplasty are fre-quently necessary to permanently cure CSOM. These procedures are readily available in tertiary centres with an otologic department, a standard service in all developed countries. Mastoidectomy involves removing the mastoid air cells, granulations and debris using bone drills and microsurgical instruments. Tympanoplasty involves closure of the tympanic perforation by a soft tissue graft with or without reconstruction of the ossicular chain. The extent of damage to the ossicular chain determines the specific type of tympanoplasty; sequential destruction of the malleus, incus and stapes requires progressively more medially placed tympanic grafts.

Mastoidectomy and tympanoplasty are two procedures that may or may not be performed together in order to eradicate CSOM, particularly if cholesteatoma is absent.[1] In both procedures, the middle ear is inspected and, if complete removal of infection warrants it, the middle ear ossicles and mucosa may be removed. The bony

1 In a study comparing 147 patients who underwent tympanoplasty with mastoidectomy and 104 who had tympanoplasty alone, graft success rates were 90.5% and 93.3%, respectively, and were unaffected by presence or absence of ear discharge. Postoperative air-bone gaps were closed within 20dB in 81.6% and 90.4%, respectively, a difference that was not statistically significant. See Mishiro et al. (119).

posterior canal wall that separates the middle ear and mastoid cavities may also be removed with drilling, stopping only to preserve the facial nerve that lies within its base. This is called canal-wall-down mastoidectomy (CWD), as opposed to intact-canal-wall mastoidectomy (ICW) in which the posterior canal wall is preserved and an opening through it is made to gain entry into the middle ear. The latter procedure conserves the anatomy of the middle ear and facilitates hearing restoration through tympanoplasty. However, the ICW mastoidectomy is more technically demanding and often leads to recurrent or residual disease because of the limited surgical access to the middle ear (156). Thus, good post-operative monitoring is required and patients must be willing to submit to a second surgery, either just to "look-and-see" or to remove recurrent or residual cholesteatoma. The CWD mastoidectomy may be easier to perform, and affords superb access to the middle ear particularly with extensive cholesteatomas. Surgical restoration of hearing may also be imperilled by the lack of graft support provided by the posterior canal wall, although recent studies demonstrated good postoperative hearing gain (17).[2] Post-CWD patients have less need to submit to frequent follow-up visits or second operations and their ear disease recurrence rates are lower (17). Often, the choice of procedure depends less on published evidence and more on patient factors as well as surgical expertise. For example, contracted mastoid air cell systems make ICW mastoidectomy virtually impossible to do.

Because of the considerable resources that each procedure entails and the factors that influence their effectiveness, it is important to determine the appropriate indications for performing each procedure among patients with CSOM and the performance conditions in which they are most effective.

Literature review

A MEDLINE search using the terms "exp tympanoplasty", "exp mastoid" and "exp cholesteatoma" was performed and the articles retrieved were limited to "review articles". The abstracts were then read and those that reported surgical results were included in Table 12.

Most of the studies were case series. Among the cohort studies, ICW mastoidectomy was compared with CWD mastoidectomy. None of the cohort studies had non-surgical treatment arms to which the effectiveness of mastoidectomy could be compared. At its best, mastoidectomy has failure rates ranging from 3% to 18% or, conversely, success rates ranging from 82% to 97% in terms of eradication of middle ear disease (e.g. cholesteatoma). On the other hand, hearing improvement occurs in

2 Postoperative recurrent cholesteatoma rates among children with CSOM were 34% for less experienced surgeons, 26% for those who had performed over 350 otologic operations, and 15% for those with as many as 1715 operations. See Soldati & Mudry (156).

Table 12. Results of mastoidectomy for CSOM

Author / year*	Country	Subjects (follow-up period)	Surgical failure rate** (% of cases)	Hearing improvement (% of cases)	Study design
Karmarkar et al./ 1995 (87)	Italy	433 cholesteatoma cases (7 yrs)	CWD: 12.38 ICW: 42.4		Cohort
Garzon Calles/ 1994 (63)	Spain	243 mostly cholesteatoma cases (5 yrs)	4.1		Case series
Vartiainen / 1995 (177)	Finland	349 cholesteatoma cases (7.3 yrs)	12.3		Case series
Vartiainen / 1995 (176)	Finland	569 non-cholesteatoma cases (5.2 yrs)		50–68	Case series
Vartiainen / 1993 (175)	Finland	431 cholesteatoma cases (6.9 yrs)	8.6 CWD: 7.7 ICW: 9.3	36 (hearing worse 28)	Cohort
Zorita / 1994 (190)	Spain	57 paediatric cholesteatoma cases (7 yrs)	17.5 CWD: 12.9 ICW:33	17.5 (hearing worse 10.5)	Cohort
Brackmann /1993 (22)	USA	108 cholesteatoma cases (5 yrs)	3		Case series
Donaldson /1992 (49)	UK	66 non-cholesteatoma cases (5 yrs)		30	Case series
Tos / 1989 (166)	Denmark	116 non-cholesteatoma paediatric cases (3–15 yrs)	9	41 (hearing worse 5)	Case series
Parisier / 1989 (51)	USA	96 ears with cholesteatoma paediatric cases (3.5 yrs)	11	25 (hearing worse 41)	Case series

* Figures in parentheses are references.
** CWD = canal-wall-down mastoidectomy; ICW = intact canal-wall mastoidectomy.

a smaller proportion of patients (18–68% of cases), the wider range suggesting significant variations in outcomes from very poor to fair. The data indicate that mastoidectomy offers a better chance of achieving the goal of CSOM resolution rather than of hearing restoration.

The effectiveness of mastoidectomy and tympanoplasty also depends on patient selection and the timing of surgery (except for patients who need emergency surgery for intracranial or extracranial complications of CSOM). This is particularly critical when performing tympanoplasty in children with CSOM in whom the procedure is technically more demanding and the results less consistently good, compared with adults. Conclusive evidence is lacking, however. A meta-analysis of 30 studies on paediatric tympanoplasties, for example, found that only advancing age correlated with higher rates of graft-take. Surgical technique, prior adenoidectomy, presence of active infection, size of perforation, status of the contralateral ear, and eustachian tube function may or may not predict better healing (168,178). When the disease is less severe, even young age may not be a risk factor. In 116 children who underwent tympanoplasty for non-cholesteatomatous CSOM and who were followed up for 16 to 27 years, the results were the same in ears operated on at the ages of 2.5 to 7 years and 8 to 14 years. In total, 14% of ears were revised during the entire observation period (167).

Practical implications

The cost of mastoidectomies will probably place them beyond the reach of most developing country populations who often have to pay for health care from their own pockets. Mobile ear clinics may provide surgical services to communities that have neither the physical access nor the financial capability to avail of tertiary care, but this requires a strong and continuous commitment and logistic support that many developing countries might not be able to sustain on their own. Even among developed countries that care for minorities with high prevalence of CSOM, issues of acceptability affect the long-term outcomes of surgical outreach programmes (179).

Moreover, technical proficiency is a direct function of training experience and frequency of performance and thus contributes enormously to the success of the procedure (168). ENT residents in developing countries may see more CSOM cases that require radical surgery and may be less adept with conservative surgery. ENT specialists are a scarce resource in developing countries and have to practise general ENT. Since many CSOM patients are poor, ENT private practice cannot be limited to purely otologic surgery, mastering the intricacies of tympanoplasty and assuring consistent results. Compliance to long-term follow-ups may also be difficult for post-mastoidectomy patients who live far from urban centres where ENT specialists have their practices. This makes a planned second-stage tympanoplasty or tympanoplasties with a second-look surgery unfeasible. Thus, even if a larger segment of CSOM patients were to gain access to mastoidectomy and tympanoplasty, long-term restoration of hearing may be less likely than permanent eradication of infection, which can be readily attained by a radical mastoidectomy. In such situations, the simplest and safest form of mastoidectomy that would control infection, without necessarily restoring hearing, should be taught to and performed by ENT specialists. These issues explain the surgical results of the observational studies included in the preceding review.

Thus, the conservative medical management of CSOM is important in three clinical scenarios: 1) when a patient cannot avail of surgery for any reason; 2) as pre-operative treatment to better achieve a dry safe ear; and 3) as post-operative treatment for surgical failures (153).

Chapter Four
Management Scenarios

By combining the results of the systematic reviews in the preceding chapters with a review of the clinical experience of several experts, we obtain the following stepwise management of CSOM under ideal conditions:

1. Perform complete examination of the ear canal, tympanic membrane and, if the perforation is large enough, the middle ear. This is best done with an otomicroscope; general anaesthesia may be required if adequate examination cannot be performed in a conscious patient (e.g. in the case of a struggling child) (21).
2. Aspirate the discharge from the middle ear and submit for culture (both aerobic and anaerobic organisms) and sensitivity studies.
3. Perform a complete physical examination to detect other related foci of infection, such as the nose and paranasal sinuses, pharynx, and lungs.
4. Carry out pure tone and speech audiograms to assess the type and extent of any hearing impairment.
5. Request X-rays of the temporal bones to assess the extent of the disease.
6. Initiate adequate aural toilet, which will be continued at home by the patient and carer.
7. Instruct patients and carers to properly instil wide-spectrum topical antibiotics such as neomycin-polymyxin for 1–2 weeks on the affected ear(s) (see Chapter 3).
8. Re-assess after two weeks. If the discharge fails to resolve, and if the culture and sensitivity results reveal *Pseudomonas aeruginosa,* change to topical quinolone or another aminoglycoside such as gentamicin.
9. If patients find it difficult to comply with daily aural toilet and topical antibiotic instillation, these can be performed in the clinic if the patient can visit daily.
10. If patients find it difficult to comply with ambulatory care, or if the discharge persists after four weeks of treatment, hospitalize the patient and administer parenteral antibiotics, selected on the basis of the culture and sensitivity results (21).
11. If the discharge resolves at any time during the period of medical management, instruct the patient to return periodically to monitor closure of the perforation or a recurrence of the discharge.
12. If the perforation does not close and the discharge does not recur, a tympanoplasty is performed to restore hearing.

13. If the perforation does not close and the discharge recurs, a mastoidectomy is performed to eradicate the infection.
14. Small polyps may be cauterized and attic cholesteatoma may be suctioned out progressively with each visit (38). More extensive lesions require mastoidectomy. Any suppurative complication also requires immediate mastoidectomy.

This management algorithm can be modified if an otological service is available and the patient has access to it. Other modifications can also be introduced depending on specific patient characteristics (e.g. age) and the clinical context in which the consultation for the ear problem is made. Five clinical management scenarios are considered:

Management Scenario 1 – Patient with a newly discharging ear, with no previous treatment.
Management Scenario 2 – Patient with a previously treated but newly discharging ear.
Management Scenario 3 – Patient with a recurrent discharging ear, with or without previous treatment.
Management Scenario 4 – Patient with a recurrent discharging ear, with ear swelling or pain or fever.
Management Scenario 5 – Patient with no discharge but with hearing loss.

Management Scenario 1

Patient with a newly discharging ear, with no previous treatment

The principal diagnostic task, given a patient with a history of persistent ear discharge for less than 2 weeks, is to differentiate CSOM from AOM (with perforation) and from AOE. The differentiating points in the history and physical examination have been discussed in the section on implications of research evidence on the diagnosis of CSOM. The difficulties in obtaining a reliable history from carers of children with CSOM have also been mentioned; primary health workers should therefore be persistent in questioning but sceptical in interpreting the responses.

Look for signs, not just symptoms

Directly asking a carer if the child has ear pain might not be reliable because very young children seldom indicate that their ears are the source of pain. Tugging at their ears and crying whenever their ears are touched are signs commonly seen among children with AOM and mothers should be questioned about this. The presence of ear pain can be immediately verified by gently tugging the pinna, and pressing on the tragus and on the mastoid bone. Tragal tenderness suggests AOE and mastoid tenderness suggests acute mastoiditis.

Ask sensitively

The way to ask about the presence of an ear discharge (or to obtain a history of ear discharge) is crucial, since this is the main clinical marker for CSOM. The concept of ear discharge might be intimately bound to one's cultural perceptions and attitudes. In the Philippines, for example, some forms of ear discharge are called luga while others are not. Luga is a special type of ear discharge which is foul-smelling and thick, and conforms to the popular notion of an ear problem frequently associated with deafness; in a very young child it is considered a serious problem that threatens hearing and should be treated immediately. It is not the same as a discharge that is due to milk from the mother spilling into the ear canal. This might not be considered serious. In an older child, especially when luga has recurred from time to time without any untoward incident, this may be considered part of growing up. Carers often think that once luga has disappeared, the disease has been cured and that a recurrence is due to a separate disease episode that would also most likely resolve on its own. The possibility that ear disease might affect the brain and lead to death is slowly being recognized but is still often denied by Filipinos with relatives who had luga during childhood, which has never recurred since then (102).

Questions about the possible presence or history of otorrhoea must be framed in the most neutral way possible. This might mean asking about (literally) any fluid in the ear canal. Usage of any local terms must take into consideration the cultural meanings attached to otorrhoea.

Get a clear view of the eardrum

The presence of ear discharge should therefore be verified regardless of the answers to history-taking questions. This should be ascertained by the naked eye with good illumination. That otorrhoea, when present, reliably identifies otitis media but that the converse is not true has already been pointed out in the research evidence cited in the section on otoscopy. Several manoeuvres might be done to increase the sensitivity of merely looking at the ear canal, such as wiping the entrance to the ear canal with a clean piece of cloth and inspecting for discharge, swabbing the canal with cotton pledgets, or asking the child to perform a Valsalva manoeuvre to see if there is a discharge from the middle ear through the tympanic perforation. If a paediatric stethoscope can be pressed against the canal entrance or if its diaphragm can be replaced by an adapter that fits the canal snugly, a popping sound may be heard when the patient does a Valsalva.

In clinics where otoscopes are readily available, CSOM can be diagnosed by the presence of a tympanic perforation, a discharge, and mucosal changes in the middle ear. Cleaning the canal of debris might be time-consuming and, with fretful children, can be very stressful to all concerned, but the accuracy of a well performed otoscopy should be weighed against the lengthy taking of an unreliable history, which can also be quite exhausting.

The duration of the ear discharge should aid in classifying the infection as acute or chronic, particularly when there is no way of visualizing the eardrum. Because it may take 2 or 3 months for 80% of AOM in children to resolve, persistence of ear discharge beyond 2 weeks does not necessarily indicate CSOM, and the diagnosis can only be made presumptively at the primary care level. All children with otorrhoea, regardless of the initial assessment, should therefore be referred to a secondary centre for confirmation of CSOM or for possible cholesteatoma formation.

Beware of danger signs

In addition, all children with otorrhoea should be screened for the general danger signs enumerated in the IMCI algorithm – i.e. history of convulsions, not able to drink, lethargic or unconscious, and vomits everything (67) – because these can be seen among CSOM patients with intracranial complications such as meningitis and brain abscess. Those with acute labyrinthitis would also be severely vertiginous and would vomit any food taken in. These patients should be treated with high-dose antibiotics, and immediately referred to a hospital where mastoidectomy may be performed. Those with acute mastoiditis would have a tender swelling behind the ears and should also be referred for tertiary care.

The IMCI guidelines also require that all children with fever and a stiff neck should be given antibiotics and referred urgently to a hospital. Patients with CSOM who display these symptoms might be harbouring intracranial complications as well as labyrinthitis, subperiosteal abscess and lateral sinus thrombophlebitis.

Patients with a facial nerve paralysis are easily identifiable with careful examination, as are patients with a tender post-auricular swelling, so that this complication should be readily recognized and urgently referred.

Teach patients and their carers proper aural toilet at the first visit

Once the diagnosis of CSOM is made, aural toilet should be performed. Suctioning the middle ear and canal under direct visualization with a head mirror, head light or an otomicroscope is best. If this is not feasible, gently irrigating the ear followed by dry mopping with cotton-tipped applicators should be attempted. Boiled plain or saline water warmed to approximately body temperature may be used; diluted vinegar or alum acetate solutions may also be tried. Hydrogen peroxide lifts debris from the ear canal because of its fizzing but its constant use might retard wound healing. It is also irritating to inflamed tissues. The patient or carer must be taught exactly how to perform aural toilet at home because frequent aural toilet alone, even if it dried up the otorrhoea in only 26% of patients included in the meta-analysis, still allows topical antimicrobials to temporarily gain entry into the middle ear.

Dry mop or, if this is not possible, wick the ear

Instilling cleansing fluids into the ear and dry mopping the cavity will take more time than simply inserting a wick, but may be more effective. That this skill can be taught to health workers and even to schoolchildren has been demonstrated in two field trials (50,155). Cleanliness must be maintained during the preparation and storage of the irrigating fluids at home, and fresh solutions must be made from time to time to guard against bacterial colonization. Ensuring the relative purity of the vinegar, alum powder, boric acid powder, alcohol and water must be emphasized. Teaching patients how to dry mop their ears gently will prevent accidental trauma to the canal and eardrum.

Ear wicking alone has not been supported by clinical trials as an effective form of treatment. However, Wilde et al. (182) observed good resolution rates in both groups of a clinical trial that compared packing the ear with wicks impregnated with TAC (tetracycline-colistin) versus filling the ear with the ointment without wicks. In mass treatment of schoolchildren with draining ears in Zaire, Mahoney (107) noted a 70–80% disappearance of otorrhoea using ear wicks impregnated with alum acetate. The wicks were changed daily and this is important. Once alum hardens, its astringent property disappears; thus the wicks have to be changed daily to keep the wicks moist with alum. With plain gauze ribbons, the wicking action stops once they are soaked with ear discharge. The IMCI guidelines recommend daily changing of the wicks to prevent maceration of the canal skin and development of AOE because of the constant presence of infected moist material. Daily ear wicking would not be practical if children had to be brought daily by their carers; having to take leave from work and travel some distance to the clinic would discourage compliance. School-based daily ear wicking, aural toilet, and topical treatment using classmates or teachers as ear monitors might work, as Smith et al. (155) demonstrated in the Kenyan trial. Again, this requires that patients and their carers are well instructed and motivated.

Refer all presumptive cases of CSOM for otoscopy

Patients must be re-evaluated after several days of aural toilet. AOE usually resolves within a week. Otorrhoea and fever from AOM should subside within one to two weeks. If possible, all patients should then be referred for otoscopic validation in a secondary or tertiary centre. Resolution of the otorrhoea and disappearance of other ear complaints may justify delaying a patient's referral, but the outpatient records must clearly indicate "presumptive otitis media case". In this way, any future recurrence of ear problems can prompt health workers to immediately refer the case after instituting aural toilet.

The possibility of declaring all cases of otorrhoea as otitis media, unless proven otherwise by otoscopy, should be considered in clinics where the diagnosis of CSOM is often made, thus leading to management of AOE, AOM and CSOM with aural toilet and topical antiseptics or antibiotics. This would be unjustified for patients with only AOM and otorrhoea from a small perforation, through which the topical agent will not be able to pass. In this type of AOM, topical antiseptics – and worse, topical antibiotics – would constitute an unnecessary expense, which would have to be weighed against failing to initiate treatment for CSOM.

Begin topical antiseptic or antibiotic treatment at the first visit

Topical antiseptic or antibiotic treatment may be initiated at the first consultation, but the health worker must ensure that patients can be trusted to clean their ears assiduously, particularly before instilling the topical agent. Many treatment failures may be traced to failure of the topical agent to reach the middle ear because of profuse discharge. Health workers might elect to initiate topical antimicrobial therapy on the second visit, once the discharge has abated by regular aural toilet.

The second visit may be scheduled one week after the first. The clinical trials in the systematic review showed that short-term outcomes, such as resolution of otorrhoea and eradication of middle ear bacteria, are observable after 1 to 2 weeks of treatment. If the otorrhoea has been reduced or has disappeared, aural toilet and topical antimicrobial therapy should be continued for at least one more week. If the latter has not been started, the second visit would be a good time to begin it.

Commercial antibiotic solutions may be used if they are available and patients have access to them. Otherwise, topical antibiotic or antiseptic solutions must be prepared, preferably in the clinic so that their quality and cleanliness can be ensured. Patients who have to prepare these solutions at home must be taught proper dilution methods and storage of both the raw ingredients and the solutions.

Make sure topical antimicrobials reach the middle ear

The actual administration of topical agents would involve keeping the patient recumbent on one side with the affected ear up. After aural toilet, several drops of the antimicrobial solution are instilled into the ear. Then the ear canal is occluded momentarily by pressing on the tragus several times. This method, called displacement, "milks" the Eustachian tube of any inspissated mucus and allows the antimicrobial solution to displace the air trapped inside the middle ear and canal, facilitating its penetration (105). The lateral recumbent position is maintained for several minutes to ensure contact of the solution with the middle ear mucosa. The whole process is repeated two or more times daily. Instilling the solution into the ear at bedtime and sleeping with the affected ear up will allow longer contact of the solution with deeper areas of the the middle ear (150).

Antiseptic or antibiotic powders, either in suspension or in the dried form, adhere longer with the middle ear mucosa but may be harder to deposit into the ear. In particular, powders are difficult to scatter throughout the middle ear and a powder blower or insufflator may have to be used. Unfortunately this device is not available in many settings and powders may have to be blown by breath to disperse them. They also tend to cake inside the canal, making them hard to remove. Often patients, even adult ones, have to depend on another person to properly administer the powders. Suspensions are therefore more convenient to use, especially when no carer is available or when dealing with a struggling, uncooperative child.

Management Scenario 2

Patient with a previously treated but newly discharging ear

Since it is possible that CSOM arises from cases of acute otitis media with perforations that have not resolved with the first antimicrobial treatment, patients with persistent ear discharge after the first visit should be treated more aggressively. Topical antimicrobial therapy, if initially deferred, should be started at this time (see previous section).

Consider antimicrobial resistance

Bacterial resistance to the topical antibiotics can be checked if there are accessible bacterial culture facilities (20,56,110,159). Adjusting the topical antibiotic spectrum according to the culture results would often mean changing from one anti-pseudomonal drug to another. The benefits of using topical ofloxacin, which has good anti-pseudomonal activity, should be balanced by its cost (see section on cost-effectiveness analysis). If the patient was initially treated with a topical antiseptic, then changing to a topical antibiotic may be considered, particularly if the culture and sensitivity test yields bacteria sensitive to a specific topical agent. However, three studies that compared topical antibiotics versus antiseptics or steroid showed little difference between the two groups (OR = 1.34, 95%CL = 0.64, 2.81) (1).

Check for patient compliance

If the patient has been on aural toilet alone, problems in complying with the daily routine of irrigating and dry-mopping the ear should be checked by asking the patient or carer to describe or demonstrate how they perform the aural toilet at home. Because daily aural toilet and topical therapy require patience and skill, patients may neglect to religiously adhere to the treatment protocol.

Antibiotic drops are often instilled without proper prior cleaning, making them useless. In these cases, discontinuing the antimicrobial agent and merely concentrating on motivating patients to maintain the aural toilet regimen may resolve the persistent otorrhoea. This is because irrigating solutions containing such acids as vinegar or boric acid lower the pH of the middle ear and inhibit the growth of *P. aeruginosa.*

Refer patients for confirmatory otoscopy

Regardless of the outcome, patients in this group should be referred to a secondary or tertiary centre for confirmatory otoscopy. The need for radiological examination of the mastoids, audiometric examinations, or culture and sensitivity tests can then be determined after otoscopic evaluation and tuning-fork testing.

Consider parenteral antibiotics

Intravenous antibiotics may be given if resources for confining patients for several days and supporting the cost of IV antibiotic treatment are available. Again, the benefits have to be weighed against the direct and indirect costs (e.g. the carer losing time from work) of IV antibiotic administration, as well as the lack of high-quality evidence supporting its short- or long-term effectiveness.

Beware of danger signs

Fever should alert health workers about an infection outside the ear. Again, signs and symptoms suggesting suppurative complications of CSOM should be checked (see above, Management Scenario 1) and proper referrals should be immediately executed.

Check for co-morbidity

Systemic antibiotic treatment may be added to the topical treatment, not to improve effectiveness since the systematic review does not support this goal, but rather to treat a concomitant upper or lower respiratory tract infection. Pneumonia may be identified in children using the IMCI protocol. The nose and throat should be visually inspected with the naked eye, aided by good illumination from a penlight. Viral and bacterial rhinitis, sinusitis, adenotonsillitis or pharyngitis can contribute to the persistence of otorrhoea. Nasal discharge, particularly when coloured, strongly suggests bacterial rhinosinusitis. In children, persistent coughing despite apparently normal chest findings should raise the possibility of chronic sinusitis. Children with sinusitis do not manifest with the classic signs of headache or sinus tenderness. White patches of exudates on the tonsils, as well as tonsillar redness or enlargement, suggest tonsillitis. In children, mouth breathing, snoring and apnoeic spells at night should necessitate a mirror examination of the adenoids to determine adenoid enlargement. Adenoid and tonsillar hypertrophy blocks the Eustachian tube and impairs the ventilation and drainage of the middle ear, leading to persistence of otitis media.

A watery nasal discharge, sneezing, tearing, or itching of the eyes, nose and throat suggests allergic rhinitis which can also promote persistence of otorrhoea. A history of exposure to inhalant allergens followed by allergic symptoms is often enough to clinch the diagnosis. Simple measures to decrease exposure to the identified allergens can then be instituted. A short course of antihistamines and decongestants can be given to relieve the symptoms, although they do not alter the course of otitis media.

Malnutrition should be concomitantly managed since immunocompromised children are more prone to chronic infections such as CSOM. Debilitating systemic infections such as tuberculosis and HIV also weaken the immune defences and may render eradication of the disease difficult (96).

The presence of other risk factors – such as ethnicity, a family history of otitis media or allergies, previous history of bottle-feeding, early onset of ear discharge, and living in crowded housing conditions – should be checked. These may be impossible to alter, but they can aid in explaining to the patient why the discharge has persisted despite good adherence to treatment.

Establish an alliance with the patient against CSOM

Because increased knowledge and attitudes on risk factors for otitis media have been shown to change behaviour (41), health workers should exploit every contact with the patient or carer to promote the following primary preventive measures:

1. Adequate identification and management of AOM.
2. Follow-up of groups at risk (children less than 5 years, children with a first episode of AOM before one year of age, children with recurrent AOM, children in day-care centres, children with a family history of otitis media).
3. Control of risk factors for OM – smoking cessation, breastfeeding, proper nutrition, proper hygiene, precautions among children attending day-care services, allergy treatment.
4. School screening programmes for hearing loss and for middle ear effusions.
5. Close follow-up of all AOM cases with ear discharge till closure of the tympanic perforation, or for at least 6 months.[3]
6. Immunizations for measles, *H. influenzae* and pneumococcal disease to prevent serious respiratory tract infections which would also predispose to otitis media.

3 Otorrhoea usually recurs after treatment within the first 6 months. See Leiberman et al.(99).

Communicating with the patient or carer is critical to keeping them on track. A therapeutic alliance must be established and any issue that would mitigate adherence to the treatment regimen should be discussed with the health care providers. The following messages have to be delivered in culturally adapted forms:

1. CSOM is a chronic disease which can cause deafness, delayed intellectual development, limited employability, disturbed social life and, if untreated, may occasionally be fatal.
2. Patients must recognize certain danger signs (e.g. fever, headache, vomiting and vertigo) which herald the spread of infection beyond the ear. Patients must promptly consult a health worker, once these symptoms appear, for possible hospitalization and ear surgery.
3. The otorrhoea in CSOM is a sign of active disease which can be treated with diligent ear care and adequate antimicrobial agents. Because this treatment must be repeated several times daily within a period of at least 2 weeks, the patient's commitment is essential to ensuring successful treatment.
4. Disappearance of otorrhoea does not mean permanent cure. Patients must be checked regularly once the diagnosis is made until the tympanic perforation heals. The ear is never safe from future bouts of otorrhoea until healing has occurred.
5. Entry of water into the ear is absolutely contraindicated. Children with CSOM must avoid exposure to cigarette smoke and crowded environments. Breast-feeding should be implemented, allergens should be identified and avoided, and upper respiratory tract infections should be treated .
6. The hearing loss in CSOM will persist usually until the perforation closes, although some degree of hearing loss may persist even when the disease has been cured. No drug will close the perforation but surgery may help in selected cases.

Management Scenario 3

Patient with a recurrent discharging ear, with or without previous treatment

This scenario applies to most patients with CSOM who, having often had recurrent ear discharges since early childhood, tried many treatments including herbal ones. Most of the subjects in the clinical trials in the systematic review are similar to this group of patients; thus, the results of the systematic review are most applicable to them.

Start antimicrobial treatment with aural toilet

Aural toilet must be initiated on the first visit. Depending on the skill and motivation of the patient or carer, a topical antibiotic or antiseptic can be added on the first or second visit. Encouraging the patients or their carers to comply religiously with the treatment regimen is more crucial here because the disease is now in the chronic and possibly irreversible stage, which may present a greater challenge because of the previous experience with recurrent otorrhoea despite occasional treatments.

Refer, as soon as possible, all patients for otoscopy, hearing assessment and possible surgery

A referral to a secondary or tertiary centre for otoscopic evaluation must be made after the first visit. If this is not possible, patients must be seen regularly at one- or two-week intervals to check on clinical improvement and ensure adherence to treatment. Non-resolution of the discharge, even after one month of adequate antimicrobial therapy, makes early referral mandatory in order to prevent the development of complications and the worsening of hearing loss. Despite the practical challenges of performing pure tone audiometry in field settings, hearing assessment should be performed particularly in children with bilateral CSOM (65,106).

Symptoms suggesting severe or dangerous ear disease merit immediate referral. Look for the presence of cholesteatoma or granulation tissue because these are common pathological changes which account for non-response to medical treatment. Elective or emergency mastoidectomy can be scheduled depending on otoscopic and/or radiological evaluation. If no serious complication has been detected by otoscopy and if the condition of the middle ear suggests a potential for healing, the patient can be reverted back to the primary level for continued medical management. Most ears with discharges will dry up depending on the patient's immune competence, exposure to risk factors, and compliance with treatment.

Patients in this scenario will probably require elective mastoidectomy, provided that adequate medical treatment has previously been administered. The purpose of continuing with medical treatment will be to prepare the ear for mastoidectomy and reduce the bacterial load before surgery. Pre-operative antibiotic administration has been shown to improve the graft's "take" and the stability of middle ear function (97).

Role and impact of ear camps and outreach mastoidectomy services

Having access to a service and facilities for mastoidectomy and middle ear reconstruction will determine the course of action which primary health workers can take at this stage. If a secondary or tertiary centre with adequate otologic expertise and resources is physically accessible and the procedure can be paid for by the patient or some form of public financing, health workers should immediately refer these patients for ENT evaluation even before deciding to place the patient on medical management. Aural toilet, however, can be initiated at the first visit.

Because of the severe scarcity of resources to perform ear surgery, outreach surgical teams or ear camps may have to be organized to address the backlog of mastoidectomies in areas with little chance of access to specialty services. In developing countries, roughly 20% of the population would not have access to basic health services. In the poorest nations, such as in Sub-Saharan Africa, this proportion could be as large as 50%. Since ENT specialists are even a scarcer commodity, these proportions underestimate the need for mastoidectomies in developing countries.

The figures in Table 13 are therefore a rough approximation. They present the number of patients in the four regions of the world with the greatest burden of CSOM, based on calculations from the previous section using 1999 population sizes and CSOM prevalence rates. The proportion of patients with CSOM who do not have access to otological services was assumed to be similar across countries for the region and similar across diseases. This might be true for large areas of Sub-Saharan Africa, India and China where the disease burden is greatest, but not for many small countries in South-East Asia and the Western Pacific where disparities in political systems and health financing schemes create large differences in equitable access to health services. In the period 1990–95, about 20% of the populations in developing countries – less in China (10%) because of its large and efficient publicly financed health care system – and nearly 50% of the people in Sub-Saharan Africa had no access to health care (172).

The regional number of CSOM patients who need mastoidectomy was assumed to be 25% of the total number of CSOM patients in the region. This is based on the failure rate of short-term medical management in the systematic review of clinical trials (1), barring racial differences in treatment response or disease severity. This is a conservative estimate because the CSOM cases that initially respond to topical treatment may, in the longer term, recur and require surgery.

Because of large differences in physician:population ratios among countries, as noted in the 1993 World Development Report (185) – India had a physician:population ratio of 1:2460; East Asia and Pacific region, 1:6170; and Sub-Saharan Africa, 1:23540 – the regional concentrations of ENT specialists would vary even more widely. Because of great disparities in financing surgical procedures, it was estimated that while about 80% of CSOM patients who need mastoidectomy in China and other Western Pacific countries could use the service, only about 50% of patients in South-East Asia and about 10% in Africa would have access to mastoidectomy. Thus, the need for outreach surgical teams would be most acute in India, and in other countries (excluding the emerging economies) in the Western Pacific and South-East Asian regions which have a large mastoidectomy backlog due to lack of access to ENT surgical services. In contrast, CSOM cases in countries in the Americas, Europe and the Middle East would have relatively no difficulty in having access to otological services.

Table 13. Regional distribution of CSOM cases without access to otological services and to mastoidectomy

Region	Population with CSOM (low prevalence estimate)	% without access to otologic services	No. of CSOM cases without access to otologic services[a]	No. of CSOM cases who need mastoidectomy[b]	No. of surgical CSOM cases without access to mastoidectomy[c]
Africa	2 407132	90	2 166 419	601 783	541 605
South-East Asia	20 790 784	50	10 395 392	5 197 696	2 598 848
Western Pacific	37 976 542	20	7 595 308	9 494 136	1 898 827
Total	61 174 458		20 157 119	15 293 615	5 039 280

[a] (Regional population with CSOM) x (% without access).
[b] 25% of regional population with CSOM.
[c] (25% of regional population of CSOM who need mastoidectomy) x (% without access).

Although there are no published formal evaluations of the effectiveness of ear camps in terms of reductions in country prevalences of CSOM, reports of patient outputs could help in estimating their efficiency.

For example, in 1995, three eight-day outreach programmes were organized by the Thai Ministry of Public Health in Myanmar (30 April to 8 May 1995), Cambodia (21–28 October 1995), and Vietnam (29 November to 8 December 1995). The enormous logistical requirements involved carrying 1 to 2 tonnes of surgical equipment (including 6 microscopes), drugs, and supplies by land and air (Thai International Airways provided free transport). The teams consisted of ENT surgeons and audiologists who screened patients by physical examination, performed mastoidectomies and tympanoplasties, and conducted audiometric testing on those with possible hearing loss (4). The results that were reported are presented in Table 14.

Table 14. Data on patients in Thai outreach programmes in three Asian countries

Country	No. of patients examined	No. of patients operated	No. of patients tested
Myanmar	772	98	190
Cambodia	768	112	120
Vietnam	3 000	167	145

In its nine years of operation, the rural treatment projects run by the National Otolaryngological Society of Thailand examined and treated some 27 000 patients in 65 of Thailand's 72 provinces and performed over 2000 major ear operations. This programme was later carried to India, with the collaboration of Indian surgeons. A total of 1500 patients underwent microsurgical operations at a cost of about US$15 per operation, excluding the cost of microsurgical and audiological equipment and the professional fees of the participating specialists (183).

Another example is the "Oye, Amigos!" programme, in which a combined group of hearing health and other medical professionals made 18 humanitarian medical and audiological trips to Tepic, Nayarit in Mexico from 1989 to 1993 (11). The group examined 1500 patients, issued over 800 hearing aids, and performed 150 surgical operations on 123 patients. Their tympanoplasty success rate, defined as an intact tympanic membrane, was 41% during the first 2 years of the project but increased to 74% during the last 3 years.

From a societal point of view, it is worthwhile adopting ear camps as a form of health technology aid if the capacity of a country to deal with the problem of CSOM is developed through the transfer of expertise from a donor to a donee country. Offering training in surgical and audiological skills is more important than donation of microscopes and audiometers in the course of the outreach programmes. Therefore, in order to respond to the needs of patients with CSOM who do not have access to otological and audiological services, ear camps must be conducted on a regular, sustained basis by the countries themselves. This means developing the local capacity of countries to provide regular ENT services in a way that would reach those segments of society most affected by CSOM – i.e. the poor.

Consider increasing access to otological services

Ultimately, the reduction in the burden of CSOM would depend on the ability of the health care system to provide timely and accessible ENT services on every occasion a child develops acute otitis media, in order to prevent recurrence and progression to CSOM.

Assuming therefore that an otological centre can be developed in a country that would be capable of providing tertiary services to CSOM cases referred from the periphery, the cost of ear camps would be the marginal cost of providing this extra outreach service above the usual cost of establishing and maintaining the otological centre. This would mean that transportation costs would not be as large as in the Thai outreach programmes and that the projects would not have to depend on volunteer specialists every time. It would also mean that the cost of expensive micro-surgical instruments would not be borne by the ear camps. Provided their use in ear camps does not incur an opportunity cost, the costs of acquisition, depreciation and maintenance of these instruments would be the same, whether they were used in the otological centre or in an outreach project.

Using mastoidectomy as a prototype service of an ear camp, the direct costs of the following items should probably be included:

1. Consumable materials (e.g. local anaesthetics, surgical drapes, sutures, etc.).
2. Transport by an all-terrain vehicle – acquisition costs, depreciated and then allocated to the actual length of time used in transporting equipment and personnel during the ear camp.

3. Labour and materials for construction / provision of temporary surgical suites.
4. Board and lodging of specialists and support staff.
5. Gifts to community liaison officers and materials for community mobilization.
6. Overtime pay for support staff.
7. Weekly earnings from clinical practice and salaries of ENT specialists and audiologists, representing the opportunity costs of personnel during absence from their usual duties in the hospital.

Since mastoidectomies and tympanoplasties take about 1 to 2 hours to carry out, and since ENT surgeons could probably perform three of these procedures daily for maximum efficiency, at least 4 surgeons would be needed to maintain a surgical output of 12 operated patients per day, or about 84 patients in a week. Patients may need to be pre-screened to facilitate processing during the ear camps. This entails considerable community mobilization and clinical attendance, which should also be costed.

Thus, the cost-effectiveness of conducting one ear camp should not only be expressed in terms of the treatment costs of 84 ears with CSOM, but also in terms of the efficiency, i.e. the cost for each percent reduction in the morbidity and mortality attributable to CSOM per year among patients who would otherwise have no access to mastoidectomy.

Time is an important factor. Patients with complicated CSOM need emergency mastoidectomies. Interventions that would rapidly and effectively address their needs are urgently needed. The cost for each percent reduction of the mastoidectomy backlog per year can then be compared with the efficiency of operating a more permanent otological facility. Note that for the same length of time (i.e. one year), ear camps in India would have less impact on the mastoidectomy backlog than, say, in Sub-Saharan Africa. Thus, the future benefits that CSOM patients would derive from them may be much less than an alternative that might initially cost more, but would reduce the mastoidectomy backlog much sooner. A central otological centre linked to local units by an efficient nationwide referral system would represent one such alternative programme.

Table 15 shows the impact of the provision of 12 ear camps in a year on the target of reducing the prevalence of CSOM among patients without access to mastoidectomies. A ear camp is manned by 4 ENT specialists working 8 hours daily and each one operating on 3 ears per day, leading to a total of 84 mastoidectomies per week. The work to be done is staggering.

Table 15. Number of ear camps in three regions and the estimated time for reducing the mastoidectomy backlog, i.e. the number of CSOM cases without access to mastoidectomy

Region	Regional population (x1000)	CSOM regional prevalence (%)	Population with CSOM	No. of surgical CSOM cases without access to mastoidectomy*	Number of one-week ear camps needed	No. of yrs of monthly ear camps (1008 mastoidectomies per year)
Africa	601 783	0.4	2 407 132	541 605	6 447	6
South-East Asia	1 485 056	1.4	20 790 784	2598 848	30 939	31
Western Pacific	1 651 154	2.3	37 976 542	1898 827	22 605	23
Total			61 174 458	5039 280	59 991	60

* Regardless of the type of mastoidectomy, the more ossicular remnants that are present the easier the tympanoplasty. See Chang & Chen (32).

The potential impact of ear camps can also be measured by the possible reduction of the burden of deafness among patients with CSOM who would otherwise have no access to otological services (estimated in Table 13 to be about 20 million among the 61 million CSOM patients in Africa, South-East Asia and Western Pacific regions). Since it was further estimated that 60% of CSOM patients would have significant hearing impairment, then about 12 million CSOM patients would stand to benefit from medical treatment in ear camps in terms of resolution of otorrhoea, closure of perforation, and possible restoration of hearing. Assuming that these 12 million patients with hearing impairment would require two visits each for some degree of hearing improvement to occur among all patients, and if about 800 patients were to be examined per ear camp (i.e. the output of the Thai ear camps in Myanmar, Cambodia and Vietnam), it would take 30 years for monthly ear camps (or 12 per year) to wipe out the backlog of hearing impairment due to CSOM. Clearly this is not feasible.

It is obvious that regular ear camps would only be effective if they are organized in a nationwide setting of a primary health care programme that would address the burden of disease from CSOM. Ear camps can then be used to seek out those patients without access to mastoidectomies and then facilitate surgery and post-operative rehabilitation. Most importantly, primary health care services can institute primary prevention which would reduce the number of AOM cases that would progress to CSOM. These measures have already been discussed in Management Scenario 2.

Such programmes have already been shown to dramatically reduce the prevalence of CSOM in the Solomon Islands (50), among Native Apaches (164), and among Maori children (72). However, no change in prevalence was observed with a similar programme among Aboriginal children in Western Australia (179).

Management Scenario 4

Patient with a recurrent discharging ear, with ear swelling or pain or fever

Refer urgently for possible emergency mastoidectomy

Patients in this scenario will potentially require emergency mastoidectomy. Acute mastoiditis with subperiosteal abscess or any intracranial complication is associated with a high morbidity and mortality; immediate high-dose antibiotic administration and surgery are indicated. If there is any suspicion that a patient is harbouring a serious complication, referral to a centre with otoscopic and fundoscopic resources and a neurological evaluation should resolve the matter.

Formal mastoidectomies are operations that are fraught with complications and should not be attempted except by trained ENT surgeons. However, patients who urgently need evacuation of "pus under pressure" should receive emergency incision and drainage of their mastoid abscesses. Provided health workers are properly taught, which is especially important in the case of small children whose facial nerve is more exposed to injury due to lack of a mastoid process, this evacuation can probably be done in an ambulatory setting while the patient is waiting for transport to the nearest surgical facility.

Start high-dose antibiotics

High-dose oral antibiotics with good penetration through the CSF barrier can also be started in the outpatient clinic. They include widely available drugs like chloramphenicol and penicillin.

Resolution of the signs and symptoms of an intracranial infection after initial drainage and antibiotic treatment should not make health care workers defer hospitalization. Intracranial abscesses and meningitis cases that initially respond to medical management are known to rupture later and kill seemingly asymptomatic patients.

Prefer surgical removal of infection to reconstruction of the middle ear

Combined tympanoplasty and mastoidectomy resulted in a dry ear in 80% and in hearing improvement in 62–78% of CSOM patients, with cholesteatoma (33) and without cholesteatoma (174). Tympanoplasty with or without mastoidectomy had similar success rates for non-cholesteatomatous ears – 15.1% versus 17.9%, respectively (10). Tympanoplasty would not be feasible in ears with severe infection and should not be attempted. If a tympanic membrane graft can be placed, the mastoid cavity should be well debrided, the posterior canal wall should be taken down, and a large meatoplasty performed to ensure mastoid drainage and ventilation, and to facilitate inspection for residual disease.

Depending on the type of mastoidectomy and tympanoplasty, these patients must be given motivation to care for their ears through regular annual check-ups and avoidance of swimming.

Management Scenario 5

Patient with no discharge but with hearing loss

Conduct hearing screening programmes, if ENT services are available

Patients who are asymptomatic but have hearing loss are difficult to identify in clinical practice. In particular, children with CSOM seldom associate hearing impairment with ear problems (65). Caregivers' assessments of the extent of hearing impairment poorly correlate with audiometric thresholds and with change in hearing status (147). If resources are available for referring children with hearing impairment for medical and/or surgical treatment, as well as for hearing amplification, then it makes sense to conduct hearing screening programmes among schoolchildren in areas of high CSOM prevalence. This helps avoid the unwanted sequelae on school and social performance of prolonged, unrelieved hearing loss.

Ideally, children who had experienced persistent hearing impairment from chronic otitis media should also be followed up even after resolution of infection since there is indirect evidence that hearing loss may persist even after resolution of CSOM (71)

Offer surgical reconstruction or hearing amplification

Patients in this scenario can be offered reconstructive middle ear surgery or, if this is not feasible, a hearing aid. Young patients who need to attend school, and patients who need to work in settings that demand good hearing should be short-listed for management. The cost and risk of middle ear surgery, and the cost of failed tympanoplasty must be compared with the cost of purchase and maintenance of hearing aids. Good tympanoplasties are for life; hearing aids must be replaced every 4–5 years. The costs of these alternatives should be compared in terms of their effectiveness in reducing the years lived with hearing loss.

A national programme for deafness prevention would greatly facilitate the provision of both alternatives at an affordable cost.

Feasibility of management scenarios

Management scenarios 1 and 2 advocate the use of topical antiseptics or antibiotics, depending on their availability. While antiseptics are cheaper, they may be harder to procure than commercially available antibiotics, unless the local government buys in bulk the raw materials for making up the antiseptic solutions. If antiseptics have initially been used and the discharge persists, then management scenario 2 raises the issue of bacterial resistance and compliance. Because commercially available antibiotic ear drops have more specific anti-pseudomonal activity and are dispensed in sealed plastic containers, bacterial resistance and contamination of ear drops are avoided. Compliance may fall, however, if the patients are asked to buy them.

Management scenario 3 recommends referral to an ENT specialist to validate the diagnosis of CSOM and to evaluate the appropriateness of therapy. Elective mastoidectomy was also suggested. Clearly, the ratio of ENT specialists to the population (Table 16) in a country affects the feasibility of carrying out these recommendations. Since the regions with the highest burden of illness from CSOM also have the lowest ENT to population ratios, general practitioners and other health care practitioners such as midwives and community health workers have to be trained in otoscopic identification of CSOM, and particularly in recognizing the danger signs of CSOM.

Emergency mastoidectomy for CSOM patients with suppurative complications clearly depends on access of patients to otosurgical services. This emphasizes the importance of prevention since cases that require this form of surgery not only have least access but also use up the meager resources of local health care facilities. It also underscores the need to establish an efficient referral system linking local, district and regional health facilities to ensure the speedy transport of cases needing tertiary care.

Management scenario 5 would be limited both by access to and by availability of otosurgical services and hearing aids. In reality, most patients who are included in this scenario may often go through life without benefit of hearing improvement unless the local health care system undertakes regular ear camps or subsidizes audiological testing and hearing aid provision.

Table 16. Regional distribution of ENT specialists per million population

Europe	42–46
America	35
Latin America	25
East Asia	15
West and South Asia	3
North Africa	18
Sub-Saharan Africa	1

Source: Peter Alberti, personal communication, 1999

Summary of the management scenarios

Each management scenario is in itself a self-contained set of recommendations that stipulates the adoption of the IMCI algorithm at the primary level with modifications, as stated in management scenario 1. The management algorithm for CSOM, proposed by the participants of the WHO/CIBA Foundation Workshop (186), has been amplified in several important ways. First, the distinction between "medical" and "surgical" ears must be made at the first encounter, even before deciding to implement the recommendations in management scenario 1. Second, referrals for otoscopy must be made by trained health workers in management scenarios 1 and 2, and by ENT specialists in management scenarios 3, 4 and 5. The urgency of referral increases as patients go through management scenarios 1 to 4. Third, health workers and programme managers should pay attention to patients in management scenario 3 who, after initial treatment, would constitute the backlog of required mastoidectomies. The possibility of conducting outreach hearing services and ear camps to improve access and address this backlog is presented as a course of action that can be collectively taken at the local government or district health level.

Fig. 4. Management Scenario Algorithm

Patient with ear discharge of 2 weeks or more

Fever, severe ear pain, headache, dizziness, periauricular swelling

Yes →

Management scenario 4:
Patient with recurrent discharging ear, with ear swelling or pain or fever
- Refer for possible emergency mastoidectomy
- Start high-dose antibiotics.
- Prefer surgical removal of infection to reconstruction of the middle ear.

No ↓

Management scenario 1:
Patient with newly discharging ear, with no previous treatment
- Look for signs, not just symptoms.
- Ask sensitively.
- Get a clear view of the eardrum.
- Beware of danger signs.
- Teach patients and their carers proper aural toilet at first visit.
- Dry mop or, if this is not possible, wick the ear.
- Refer all presumptive cases of CSOM for otoscopy.
- Begin topical antiseptic or antibiotic treatment at first visit.
- Make sure topical antimicrobials reach the middle ear

↓

Discharge disappears after 2 weeks of treatment

Yes →

Follow up for recurrence:
- If discharge recurs – **management scenario 3**
- If discharge recurs with headache, fever, dizziness, etc. – **management scenario 4**
- If discharge does not recur for at least one year – **management scenario 5**

No ↓

Management scenario 2:
Patient with newly discharging ear, with previous treatment, still with discharge
- Consider antimicrobial resistance.
- Check for patient compliance.
- Refer for confirmatory otoscopy.
- Consider parenteral antibiotics
- Beware of danger signs.
- Check for co-morbidity.
- Establish alliance with patient against CSOM.

↓

Discharge disappears

No ↓

Patient has fever, ear pain, headache dizziness, periauricular swelling

Yes →

Management scenario 4:
Patient with recurrent discharging ear, with ear swelling or pain or fever
- Refer *urgently* for possible emergency mastoidectomy
- Start high-dose antibiotics.
- Prefer surgical removal of infection to reconstruction of the middle ear.

No ↓

Management scenario 3:
Patient with recurrent discharging ear, with or without previous treatment
- Start antimicrobial treatment with aural toilet.
- Refer as soon as possible for otoscopy and possible surgery.
- Consider outreach mastoidectomy services.
- Consider increasing access to otologic services.

↓

Discharge disappears

Yes →

Management scenario 5:
Patient with no discharge but with hearing loss
- Offer surgical reconstruction or hearing amplification

No ↓

- Refer for possible mastoidectomy
- Prefer surgical removal of infection to reconstruction of the middle ear.

Impact of management scenarios

Table 17 is an extension of the previously presented incremental cost-effectiveness analysis in Table 11. The interventions are grouped by the management scenarios that recommend them. The impact of the different management scenarios is expressed in terms of absolute risk reductions and the number of dry ears resulting from applying the management scenario on the total number of CSOM cases in Africa, South-East Asia and Western Pacific regions. The absolute risk reductions are the differences in event rates between treatment and aural toilet as reported by the systematic review or individual trials. The incremental cost-effectiveness ratios are obtained by dividing the difference in costs (between the intervention specific for the management scenarios and aural toilet alone) by the absolute risk reductions. The last column is obtained by multiplying the estimated total population of CSOM cases in South East Asia, Western Pacific and Africa regions by the event rates in the second column.

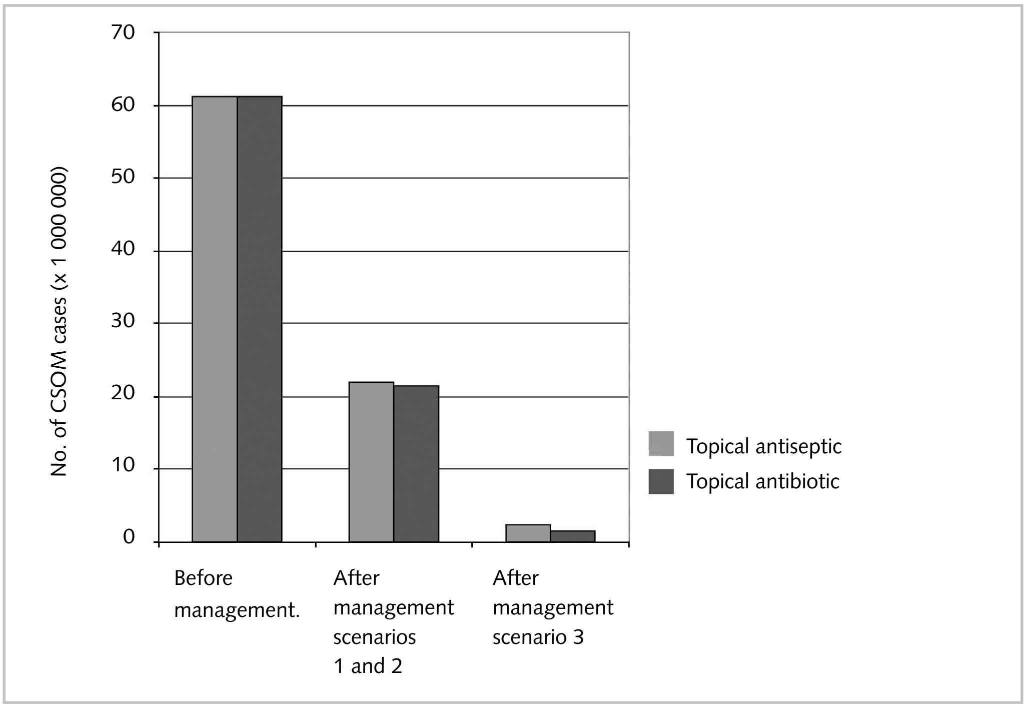
In calculating the resulting number of dry ears for management scenario 3, two values are calculated depending on whether one starts with topical antiseptic or with topical antibiotic treatment. The resulting number of dry ears would then be halved by systemic antibiotic therapy. This 50% success rate is lower but more realistic than the 100% short-term resolution of otorrhoea obtained by Fliss et al (58) following intravenous mezlocillin and ceftazidime. The Fliss trial not only used more expensive antibiotics but also hospitalized patients, making it less applicable to developing country settings.

Figure 5 illustrates the short-term reduction in the number of draining ears in Africa, South-East Asia and Western Pacific regions, as a result of management scenarios 1 and 2. Thus, a 50% reduction in the number of CSOM cases can be effected by topical antimicrobials in management scenarios 1 and 2. The remaining number is halved by intravenous antibiotics in management scenario 3.

Table 17. Cost-effectiveness analysis of alternative treatments to ear wicking, in terms of resolution of otorrhoea (see Table 11)

Management scenarios	Treatment	Cost/100 patients treated (USD)	No. of dry ears/ 100 patients treated	Absolute risk reduction (for otorrhoea)	Incremental analysis: Cost-effectiveness ratio (USD per dry ear)	No. of CSOM cases with dry ears after treatment (assuming 61 174 458 CSOM cases in Africa, South-East Asia and Western Pacific regions)
	Aural toilet alone (base case)	30	26	–	–	–
1, 2, 3	Topical antiseptic	60	64	14	2.14	39 151 653
	Topical antibiotic	250	65	43	5.12	39 763 397
3	Oral and topical antibiotics	1 940	50	32	79.6	19 575 826–19 881 698
3	Parenteral antibiotic	48 300	100	92	524.67	
3	Parenteral and oral antibiotics	13 240	50	27	489.26	

Fig. 5. Comparison of proportions of dry ears between topical antiseptic and topical antibiotic treatments in management scenarios 1,2 and 3.



The short-term effectiveness of medical treatments in terms of restoration of hearing (Table 18) has been addressed by one RCT (155) included in the systematic review by Acuin et al (1). However, this RCT compared aural toilet alone versus oral and topical antibiotics versus no treatment. Other treatments recommended by the management scenarios have not been evaluated by RCTs in terms of restoration of hearing.

The effectiveness of either elective or emergency mastoidectomy has also not been subjected to a formal RCT. The evidence for management scenario 4 is based on the life-threatening condition and the clear therapeutic effect of mastoidectomy, very similar to that of draining an abscess. Thus, the impact of surgery cannot be directly calculated using cost-effectiveness analysis.

Table 18. Cost-effectiveness analysis of alternative treatments to ear wicking, in terms of restoration of hearing

Management scenarios	Treatment	Cost/100 patients treated	No. of healed perforations/ 100 patients treated	Relative risk reduction (otorrhoea)	Incremental analysis Cost-effectiveness ratio	No. of CSOM cases with healed perforations after treatment (N = 61 174 458)
	Aural toilet alone (base case)	30	13	–	–	–
3	Oral and topical antibiotics	1 940	14	1	1 910	8 564 424

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