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The Epidemiology, Treatment Methods and Costs of Otitis Media on the Pediatric Population

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THE EPIDEMIOLOGY, TREATMENT METHODS AND COSTS OF OTITIS MEDIA
ON THE PEDIATRIC POPULATION

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COSTS AND CONSEQUENCES OF OTITIS MEDIA IN THE PEDIATRIC POPULATION

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Introduction

Next to the common cold, otitis media is the most prevalent disease diagnosed in children in the United States. Based on that fact, extensive research has been performed on the subject including everything from risk factors and treatment methods, to long term effects of recurrent disease. Even with all the research and clinical studies which extend as far back as the seventies, questions pending best treatment methods, risk factors, and burden of illness on society still persist. The intent of this paper is to summarize the current knowledge about acute and recurrent otitis media. By examining the epidemiology, present treatment methods and economic costs of otitis media on the population, the burden of illness of society will be assessed, providing the pharmaceutical industry with incentive to continue research into cost-effective medical interventions.

Pathogenesis

The term otitis media encompasses a range of diseases, from acute to chronic and with or without symptoms. In defining the terms of the disease, otitis media means an inflammation of the middle ear, without reference to etiology or pathogenesis while acute otitis media is defined as the rapid and short onset of signs and symptoms of inflammation in the middle ear. As a result of otitis media, fluid becomes trapped in the eustachian tube. This liquid resulting from otitis media is referred to as middle ear effusion. The effusion may be classified as either serous – thin, watery liquid; mucoid – thick, viscid, mucus-like liquid; or purulent – pus-like liquid. Middle ear effusion that persists for longer than three months following an episode of acute otitis media is termed chronic otitis media with effusion.
Acute otitis media (AOM) most commonly results from dysfunction and poor drainage of the eustachian tube. As a result of reflux of microorganisms present in the nasopharynx into the tubular lumen and their subsequent replication, fluid accumulates in the middle ear and subsequently may become infected. Fluid accumulation and reflux of microorganisms into the middle ear may result from high negative middle ear pressures, high positive nasopharyngeal pressure, or abnormal patency of the nasopharyngeal opening of the eustachian tube. In addition, high pressure caused by sneezing or crying may force secretions into the ear or abnormal patency of the tube can leave the tube open at rest or result in excessively low resistance to reflux.

The same pattern for the pathogenesis of acute otitis media is likely to be followed in most children: the patient has an antecedent event (due to allergy or infection) that results in congestion of the respiratory mucosa throughout the respiratory tract, including the nasopharynx, eustachian tube, and middle ear. Accumulation of the liquid that results in eustachian tube obstruction can also be due to adenoidal hypertrophy or in rare circumstances, tumor or stenosis. Generally, infection or other inflammation of the respiratory mucosa precipitates the fluid accumulation in the middle ear. Antecedant viral upper respiratory tract infections are considered the major risk factors for the occurrence of AOM.

Normally, the eustachian tube has three functions: to equalize the pressure between the middle ear and nasopharynx, to prevent reflux of nasopharyngeal secretions, and to clear secretions from the middle ear. Impairment of any of these functions may result in AOM.
### Epidemiology – Risk Factors

Acute otitis media is considered a disease of infancy and early childhood. Epidemiological studies have demonstrated that the peak incidence of otitis media occurs in the first two years of life. A study conducted from 1975 through 1984 in the Greater Boston area determined that the highest age-specific attack rates for acute otitis media occurred in the second half of the first year of life. In concurrence, results from two Finnish studies indicate that the highest incidence rates occur between 10 to 12 months of age. The high incidence in the early years of life is a consistent finding throughout the published literature. But unlike the studies above that found attack rates highest after six months of life, high incidence of otitis media was noted within the first three months of life in Nashville, Tennessee and Cleveland. All in all, specific physician visit numbers seem to support the research findings regarding age specific attack rates.

Between 1975 and 1990, physician visit rates were found to be highest among children under the age of 2 years for principal diagnosis of AOM. Some researchers explain the susceptibility of infants to otitis media by correlating the peak of incidence with the lowest levels of serum antibody (i.e. after the disappearance of the passively transferred maternal antibody and before the development of natural immunity). Others researchers implicate anatomic changes in the eustachian tube. A combination of both factors could explain the high incidence in children under five. In 1993, 28 million cases of acute ear infection were estimated to have occurred in the United States, with 98% receiving medical attention.

Unlike acute otitis media, the prevalence of chronic otitis media with effusion is not well known. Several studies have reported various estimates of the prevalence of
asymptomatic serous otitis media according to age. Rates vary from 13% at age 1 year, 14% at age 2 years, 10% at age 3 years, and 2.8% among 7 and 8 year old children. In 1993, the cases were estimated at 1.4 million for American children under 5 years of age. Another authority corroborates this with the statistic that persistent middle ear effusion occurs in approximately 10% of the cases. With rates such as these, otitis media can easily be classified as one of the most commonly diagnosed childhood diseases. They also support the need for intervention to reduce the burden of illness.

During the first five years of life, about one out of every three office visits to a physician result from middle ear disease. In a study of 2,565 children followed from birth to age two years, greater than 80% of the children had at least one attack of AOM and almost 25% had three or more attacks. Additional data from the CDC supports this statement. In 1990 for children under 15, otitis media represented the most frequent diagnosis in physician office practices. There has also been reported an increased incidence of acute otitis media and otitis media with effusion in certain immunocompromised children, including those with human immunodeficiency virus infections. In looking at specific numbers the incidence of disease can easily be seen. As indicated, the percentage of children diagnosed with otitis media decreases as age increases. This inverse relationship supports the theories of low level antibodies and eustachian tube changes as the biological basis for increase in incidence in children under 3 years of age. The numbers validate the need for public health concern in regards to this disease and emphasize the extent that the burden of disease has on the population.

Much research has been done in regards to the risk factors for otitis media and childrens’ susceptibility to ear infections. Due to the eustachain tube being shorter and
more horizontal in infants than older children and adults, infants tend to be more prone to
the disease. The basic physiological make up of an infant puts them at risk to retain fluid
in the tube.

Younger age is also a risk factor for recurrent disease. Children whose first
infection occurs in the first 6 months of life are at greater risk for severe, recurrent otitis
media. Numerous studies support the finding that age at the time of first episode of
acute otitis media can be a predictor to recurrent and chronic otitis media.

Among children, the risk factors for otitis media are many. Although some
studies point to male gender as a specific risk factor for OM, this finding has not been
seen consistently. In Greater Boston, it was determined that male gender was
significantly associated with increased risk. The study corroborated this finding by citing
the observation that epidemiological studies on bacterial infections in infancy point to
male gender as a risk factor. In addition, a panel report on the epidemiology and natural
history of otitis media states that males have more episodes of acute otitis media, more
recurrences and more severe disease than females. Greater numbers of episodes of
otitis media in males have also been noted in a prospective study of otitis media in 2253
Pittsburgh area infants. The study found that the proportions of days with effusion was
higher in boys than girls in the second year of life. Unlike the studies indicated above,
specific visit data provided by the CDC does not find a statistically significant difference
rate between males and female with regards to otitis media visits to the physician.

Another authority agreed, stating, as with most bacterial infections, boys are more likely
than girls to have recurrent infections, but the difference is not striking. Because of the
inconsistent findings, gender should not be considered an important host risk factor for
The panel report mentioned above cited one article to support the male gender bias. Strachan et al. looked at 7 year old children of smokers to draw this conclusion. One study should not be generalized to the whole sub-population of children. Gender does not appear to play a strong role in the occurrence of otitis media in children.

Race is also considered a risk factor for otitis media by some researchers and has also been inconsistently documented in the literature. The CDC indicates that visit rates for a principal diagnosis of otitis media were significantly higher for white children under the age of fifteen than for black children in the same age group for the years 1980, 1985, and 1990. It has not been determined if this reflects healthcare utilization or biological difference. Unlike the national numbers, a study of 2253 Pittsburgh infants revealed the cumulative proportion of days with otitis media with effusion higher among black infants than white infants in the first year of life. The researchers attributed the difference in their study compared to seven others which found higher incidence rates among whites to be due to differences in rates of observation of the children, or in accuracy of detection of otitis media, or both. In another prospective study of 2,500 children initiated in the 1980s, researchers found that Hispanic children had more episodes of acute otitis media than white children, with both groups having more episodes than black children.

Other races have also been found to be at increased risk for otitis media. Native American, American Eskimo and Canadian Eskimo children have been found to have an extraordinary incidence of severe acute otitis media. Complications such as perforation of the tympanic membrane, persistent suppurative drainage from the middle ear, and destruction of the ossicles are observed frequently among these children. Few studies to explore the biological reasons for the differences among the races have been done,
therefore confounding variables may account for these findings. Flaws in the studies such as in the selection of the study population (cases versus the controls) could account for racial biases, ultimately resulting in higher visit rates for one race versus another. This could also account for complication rates as reflected by the Eskimos. Other variables may also account for these results such as access to healthcare. Currently, the significance of the differences observed among races cannot be fully evaluated based on the available evidence.

Another host risk factor for acute and recurrent otitis media is familial occurrence. A positive family history for the infection is the most significant predictor of otitis media in children.\(^3\) It has been determined that children born into households with parents and siblings who have had severe ear infections are at risk for a similar pattern of disease.\(^2^1\) A meta-analytic review of the risk factors for acute otitis media determined that the likelihood of a child developing acute otitis media is two to three times higher in a child with a family history of the disease.\(^2^2\) In the Greater Boston prospective study, it was found that the strongest predictor of recurrent otitis media was sibling history of the disease. Such a history increased the risk for recurrent acute otitis media more than twofold.\(^6\) Additional studies support genetics as an important risk factor, presumably involving anatomic, physiologic, or immunologic factors.\(^2^3\)\(^2^4\) Based on strong findings in the literature, family history seems to be a significant risk factor for otitis media.

A predominant environmental risk factor for otitis media cited in the literature is daycare attendance. In an epidemiological study of otitis media, it was determined that daycare attendance was significantly related to early onset of the disease. Several daycare variables were significantly related to AOM by age 6 months, including entry at
2 months of age or younger, daycare centers, attendance ≥30 hours per week, ≥5 children in the day care setting, and ≥2 children 2 years of younger. Supporting this finding, the Pittsburgh prospective study found that during both the first and second years of life, infants in daycare had higher cumulative proportions of days with middle ear effusion than did infants at home. Overall cumulative proportions of days with middle ear effusion increased as time in daycare increased and as the number of children in the daycare setting increased. An additional study in Boston that looked at enrollment in daycare centers determined that attending daycare for ninety days or more during the first year of life almost tripled the risk of recurrent AOM by the first birthday. The foundation of this risk factor is built upon the incidence of upper respiratory tract infections in the daycare setting.

The increased risk of acute otitis media due to daycare attendance is most likely attributable to greater exposure to respiratory infections. For children younger than one, those in daycare were significantly more likely than those in home care to have otitis media as a complication of upper respiratory infections. Internationally, daycare attendance also remains a risk factor. In an international medico-economic survey of 2007 children with recurrent nasopharyngitis and acute otitis media, researchers found 45% of the children in a daycare setting, school or in the community encountered recurrence of infection. The study did not include actual numbers in the results section preventing a comparison between the settings.

Unlike the strongly supported risk factors above, exposure to smoking is another risk factor that is inconsistently supported in the literature. In the international medico-economic survey, it was determined that exposure to smoking was a risk factor for
recurrent disease. The mean percentage of patients included in the study exposed to smoking whom developed recurrent otitis media was 29.4%. In a study of passive smoking on children, researchers found that exposure to either parent smoking presented an odds ratio range of 1.0 to 1.6 for infection with acute otitis media and 1.48 for infection with recurrent otitis media with a 95% confidence interval (1.08-2.04). A third study also incriminates smoking as a risk factor for otitis media. The prospective study of Pittsburgh area infants concluded that the number of smokers in the household was related to an increase in the number of days with middle ear effusion during the first year of life. Two studies reviewed did not find smoking to be statistically significant with an increased risk of OM after multivariate analysis. Studies that have looked at smoking are difficult to compare. Some have used self-reporting as a way to monitor exposure to smoking, while others have measured urine concentrations of cotinine. These differences in measurement could result in the inconsistencies among the studies.

Non breast-fed babies have been reported as having a higher incidence of acute otitis media thus implicating formula feeding as a risk factor. The literature shows support of the breast milk as a protective measure against AOM. In a meta-analysis of the risk factors associated with acute otitis media, Uhari and colleagues found breast-feeding for at least three months lowered the relative risk of acute otitis media to 0.87 and the relative risk for recurrent otitis media to 0.69. The prospective study in Greater Boston found similar results. During the first year of life, breast fed infants were at lower risk than infants who were exclusively bottle fed for either AOM or recurrent AOM. Similar associations were also noted in studies in India, Denmark and New York.
Another environmental risk factor considered in the literature is season of birth. Once again though, there are variable findings in the research. In temperate climates, otitis media is a strikingly seasonal disease, occurring predominantly during the cold weather months. This seasonal incidence parallels the seasonal variations of respiratory tract infections. Most infants with recurrent acute otitis media improve during the late spring with renewal of disease in the fall. Because of this increased opportunity for exposure during the winter months, some studies find higher incidences of acute otitis media in children born in the fall. Due to their early lives taking place during winter and spring, peak season for respiratory illness, infants born in the fall experience increased opportunity to upper respiratory infections. Contradicting these finding are two known studies that did not find a statistically significant association with risk for AOM and the season of birth.

The use of pacifiers as a risk factor has been cited in a limited number of European studies. Use of a pacifier was found to increase the risk of recurrent acute otitis media in Finnish children attending daycare. More than three episodes of acute otitis media occurred in 29.5% of children younger than two years old using pacifiers and in 20.6% of those not using them; in children two to three years old, the incidence of recurrent acute otitis media was 30.6% and 13.2% respectively. Sucking on a pacifier may help to force fluid into the middle ear.

A final environmental risk factor referenced in the literature is poverty. Inadequate medical care, crowded living conditions, and poor sanitation have been associated with severe and recurrent acute otitis media. Perforation was present in 0.4% to 33.3%, otorrhea occurred in 0.6%-4.4%, and mastoiditis occurred in 0.19% to
0.74% of children in community and school studies in developing areas of Africa, Pacific Islands, and Southeast Asia. In Paradise’s and colleagues’ study of 2253 Pittsburgh-area infants, they also found one of the most important risk factors for otitis media to be low social economic status. It seems obvious that poor sanitation and limited healthcare access would result in greater respiratory infections and in turn more AOM. But unlike the studies referenced above, the Greater Boston prospective study did not find socioeconomic status to be a risk factor. Once again the literature is divided on poverty as a definitive risk factor for acute otitis media.

The strong risk factors consistently supported in the literature point to age of onset, familial history and daycare attendance. Identifying and trying to prevent the major and minor risk factors for otitis media may help limit the morbidity and sequelae of the disease. Ultimately, this would lessen the burden of illness on the population.

**Etiology**

The majority of cases of acute bacterial otitis media results from three major pathogens: *Hemophilus influenzae, Branhamella catarrhalis, and Streptococcus pneumoniae*. The two former tend to cause less severe disease and have a greater likelihood of spontaneous resolution while the latter is the leading cause of AOM and is less likely to resolve spontaneously. In addition to bacterial sources, viruses, alone or in combination with bacterial pathogens, can be isolated in about 20% of the cases of AOM. Most commonly implicated are respiratory syncytial virus, rhinoviruses, adenoviruses, and influenza viruses.
Clinical Presentation

As a result of infection in the eustachian tube, the child will experience pain and inflammation of the eardrum. General symptoms of acute otitis media that lead to suspicion include fever, irritability, fussiness, restlessness during sleep, ear tugging and diminished appetite in a child with an upper respiratory tract infection.\textsuperscript{14} Fever occurs in one to two thirds of children, and high fever is unusual unless accompanied by bacteremia or a significant focus elsewhere.\textsuperscript{2}

After every episode of acute otitis media, fluid persists in the middle ear for weeks to months resulting in otitis media with effusion.\textsuperscript{21} The average time with effusion, after acute infection, is 2 to 4 weeks.\textsuperscript{18} Unlike acute otitis media, otitis media with effusion will result in many different symptoms. The only symptoms may be discomfort or behavior changes.\textsuperscript{1} Longitudinal studies of otitis media with effusion show spontaneous resolution of the condition in more than half of children within three months from development of effusion. The rate of spontaneous resolution remains constant after three months so only a small percentage of children experience otitis media with effusion lasting a year or longer.\textsuperscript{1}

Diagnosis

Depending on the presenting symptoms and patient history, diagnostic methods differ for determining otitis media. Diagnosis of acute otitis media should include evaluation of signs of fluid in the middle ear along with signs or symptoms of an ear infection (bulging eardrum usually accompanied by pain or perforated eardrum, often with drainage or purulent material).\textsuperscript{1} Often physicians make the diagnosis solely on inspection of the tympanic membrane. To make an adequate diagnosis of acute otitis
media, physical examination of the patient, including pneumatic otoscopy, should be
employed after taking a thorough history. Because of the overlap in the clinical profile of
acute and chronic otitis media, it is difficult for physicians to distinguish between the two
diseases unless the patient has been observed over a period of time before the onset of the
disease or there are associated symptoms such as fever or ear pain. Physical exam
should include adequate examination of the head and neck that could lead to
identification of a condition that may predispose to, or be associated with, otitis media.
In addition, physical exam should include examining the external ear, nose, pharynx, and
palate for presence or absence of infection.

After physical exam, the otoscopic examination should take place. Examination
of the tympanic membrane should include the position (neutral, retracted, or bulging),
color, opacity, mobility to both positive and negative pressure, and the presence of other
findings such as retraction pockets or tympanosclerosis. A positive diagnosis of acute
otitis media would reveal the position of the membrane to be full to bulging, color to be
red (could be pink, yellow, or white), translucency to be opaque, and mobility to be poor
when both positive and negative pressures are applied.

Otitis media with effusion would reveal slightly different signs. Position of the
tympanic membrane would be retracted with a white (or yellow or blue) color.
Translucency could be opaque or translucent and mobility would be poor when both
positive and negative pressures are applied. Tympanometry may also be used to confirm
suspected otitis media with effusion. Because the strengths of tympanometry and
pneumatic otoscopy offset the weakness of each, using the two tests together improves
the accuracy of diagnosis.
In regards to chronic otitis media with effusion, an additional test is suggested to ensure an adequate diagnosis. Although it may be difficult to perform, hearing evaluations are recommended for children that have had otitis media with effusion present bilaterally for 3 months. A change in the child’s hearing threshold is both a clinical outcome and possible indicator of the presence of chronic otitis media with effusion.¹

**Complications**

Possible complications of acute and recurrent otitis are many, although less common today with the advent of antibiotics. Less common complications include meningitis, brain abscess, and lateral sinus thrombosis.² More common complications occur in the intratemporal region and include acute and chronic perforation of the tympanic membrane, chronic suppurative otitis media, mastoiditis, cholesteatoma and retraction pocket, adhesive otitis media, tympanosclerosis, and ossicular discontinuity and fixation. The most frequently cited contemporary sequela is hearing loss.²

The fact that mild or moderate hearing loss can be associated with otitis media has called into question what impact the loss of hearing has on child development. Research has been directed at determining the possible relationships between early life otitis media and developmental impairments in speech, language, cognition, and psychosocial function. The concept is that hearing impairment results in “auditory deprivation” during presumably critical or sensitive developmental periods within the first few years of life. It is felt that this deprivation, in turn, results in developmental disruptions that persist long beyond the time that otitis media resolves and hearing returns to normal.³⁵ However, no consistent, or reliable evidence exists that otitis media with effusion has
such long-term effects on language or learning. The studies on this subject have been inconsistent and contradictory and their study designs have been questionable. Association does not reflect necessarily causation.

**Interventions**

Even with this lack of consistent evidence on long-term development, most clinicians are usually eager to treat patients so that hearing returns to normal quickly. Several treatment methods are available today and may vary greatly depending on the clinician and the type of otitis media with which the patient is presenting. Choices include antibiotics, observation, immunization, and surgery.

Antibiotic treatment has been available since the late nineteen forties and has greatly reduced the number of complications associated with otitis media. The frequency of mastoidectomy associated with AOM in 1938 was 20%, by 1948 after the introduction of sulfonamides and penicillin, the incidence of the complication was 2.5%. Medical management appears to be the treatment method preferred in the United States, with antibiotic prescriptions leading the way. Medications were ordered or provided at 78.5% of the visits with a principal diagnosis of otitis media in 1975; the corresponding percentage was 84.1 for 1990. In 1980, 1985, 1989, and 1992, antimicrobial agents were the second leading therapeutic category of drugs prescribed by office-based physicians in the United States. During this time period, Amoxicillin was the most frequently prescribed medication for a principal diagnosis of OM. Amoxicillin remains the medication of choice for treatment of the uncomplicated case of AOM because it continues to be effective, safe, and relatively inexpensive. There are currently thirteen antibiotics all together that are approved by the FDA for treatment of acute otitis media.
All of them have demonstrated clinical efficacy for treatment of AOM and may be selected as potential alternatives to amoxicillin based on the features of the illness and other factors unique to the child and family.²¹

In children with recurrent otitis media, one method of treatment considered is prophylactic antibiotics. The most widely recommended criteria for prescribing prophylactic antibiotics are three or more episodes of acute otitis media within six months or four or more episodes within twelve months.³ The drug of choice appears to be sulfisoxazole due to the largest body of supporting data for efficacy.⁵

With the increased use of antibiotics comes the concern regarding drug resistance. Because of the frequency of infectious diseases in the outpatient setting, antibiotic drug use is likely to increasingly contribute to the continued emergence of resistance.³⁶ Ultimately the concerns regarding drug resistance have lead to the concept of observation versus prophylactic treatment for recurrent otitis media. Both theories are controversial.

The rapid emergence of antibiotic-resistant bacteria, particularly penicillin- and cephalosporin-resistant *S. pneumoniae*, represents a particular problem for the pediatrician. This bacteria is the most common cause of AOM and of more serious invasive infections such as pneumonia, bacteremia, and meningitis in children.³ Children at the highest risk of infection with resistant *S. pneumoniae* are more likely to attend daycare, to have had previous episodes of AOM, and to have received antimicrobial therapy within the prior month.³ With risk factors such as these, it is easy to see why resistance is on the rise. Because of the increase in drug resistant bacteria and the fact that a number of cases of AOM result in spontaneous resolution, Northern European countries have been advocating observation versus treatment. After reviewing the
literature for controlled trials of antibiotics against placebo, Del Mar and Glasziou determined that because 60% of the children in the trials had their pain resolved within 24 hours of presentation, the number of children who would benefit from the 40% reduction of pain afforded by treating initially with antibiotics was modest. They converted the above information into absolute risk and benefit and determined 20 children had to be treated using antibiotics in order to prevent one child from experiencing pain 2-7 days after presentation. 37 Twenty children was derived from the following: since 14% of the children will still have pain, the number needed to treat is \[\frac{1}{(0.14 \times 0.36)} = 20.\] 38 In addition, a study in the Netherlands comparing the efficacy of antibiotics alone, myringotomy alone, a combination of the two and no treatment concluded that children who did not receive any treatment had a similar outcome to children receiving one or more forms of treatment. 39 This study has led some to advocate for observation rather than treatment.

A clinician needs to determine if the relative risks of complications outweigh the benefits of antibiotic treatment, if the risks of withholding treatment and the possibility of decreasing drug resistant bacteria outweigh the efficacy of antibiotics. In closer examination of the aforementioned Netherland study, the results show that the number of children who experienced perforation, or an increased duration of pain and discharge was greater in the non-treatment group than in the group receiving antibiotics. 14 It has also been determined that the rate of acute mastoiditis has increased recently. This is attributed, in some cases, to withholding antibiotics or use of drugs with limited spectra of activity. 40 Analyzing the literature proves the efficacy of withholding treatment to appear limited. Currently there is no way to predict which children will have
spontaneous resolution and which will not. Until there is, several American opinion leaders advocate treatment of AOM.\textsuperscript{14,21,34}

A technique that can be used to prevent recurrent acute otitis media is active immunization. Among current licensed bacterial vaccines, only the pneumococcal vaccine has been shown to be of any benefit to children with recurrent acute otitis media.\textsuperscript{5} However, several studies have shown either no or minimal protection in children under the age of two.\textsuperscript{5} Although not universally recommended, immunization of children 2 years of age and older who have a history of recurrent AOM might be considered.\textsuperscript{3}

In addition, the small proportion of acute otitis media that is caused by influenza virus may also be prevented by immunization using the influenza A vaccine. Some authorities on otitis media recommend influenza immunization for children over six months that are at a high risk of acute otitis media, while others feel the influenza vaccine, as with the pneumococcal vaccine, should be considered only for the occasional older child who continues to have severe, recurrent disease.\textsuperscript{3,5}

Future immunization possibilities consist of \textit{S pneumonia} and \textit{H influenza} type B polysaccharide conjugate. Awaiting FDA approval is a new streptococcus pneumonia vaccine that is effective in infants. Physicians from Kaiser Permanente Vaccine Study Center in California tested the vaccine on more than 38,000 children and found the vaccine reduced meningitis and bloodstream infections by 90\%.\textsuperscript{41} This is the first time a vaccine has been proven to provide protection in infants. As a result of providing protection against pneumococcus bacteria in the infant population, the number of AOM cases may be greatly reduced. Another vaccine in clinical trials is \textit{H influenza} type B polysaccharide conjugate which is trying to obtain the same benefits as the presently
FDA approved Hib polysaccharide vaccine in circulation. One of the benefits of the present vaccine is the reduction of nasopharyngeal carriage of Hib in a highly Hib vaccinated population. However, plain Hib polysaccharide vaccine is only effective in children over 18 months of age which misses a large portion of the high risk AOM population. Because of this, Hib polysaccharide conjugate vaccine, which provides protective immunity after as few as two doses in the first 4 to 6 months of life is under investigation. It is likely this vaccine will be licensed in the next year. Changing to a conjugate and allowing for earlier protection will enable the vaccine to be used on the highest AOM risk children.

A final method of treatment for recurrent otitis media is surgery. For children who have had bilateral effusion for at least three months and who have a bilateral hearing deficiency, bilateral myringotomy with tube insertion becomes a treatment option. Three clinical trials during the eighties and early nineties revealed that myringotomy and tympanostomy tube insertion are effective for prevention of recurrent acute otitis media in otitis media prone infants. Data reveals that this is an option frequently considered. For example, in Montreal, Canada from 1981 to 1983, 909 3-year old children had 969 surgical interventions for myringotomy with ventilatory tube insertions. Another study in the United States estimated rates for tube insertions to be 21.2 per 1000 children who had any otitis media diagnosed during the year. Because tube insertions are performed under general anesthesia in young children, the risks of anesthesia and the surgery itself need to be evaluated. In calculating the risks for two specific complications of myringotomy with tympanostomy tube insertion, it shows that tympanosclerosis might occur after this procedure in 51% of the children,
and postoperative otorrhea in 13% of the children. In addition, tubes themselves may have some long-term morbidity, if only in the changes they may cause in the tympanic membrane, and they are costly. Because of the risks related to surgery and the efficacy of the tube placement largely confined to the time they are in the ears, the literature suggests that surgery be considered only after prophylaxis has failed.

**Costs**

The burden of otitis media on the population is easily seen through its high incidence rates. With the high incidence, the burden becomes more than just pathological but economical as well. The disease weighs heavy on the family, providers, and third party payers. In the United States alone, the socioeconomic costs may exceed 3.5 billion dollars a year in direct and indirect costs. The costs are made up of physician visits, medications, surgery, and parental loss of wages and increased child care costs.

In first focusing on the burden on the family, loss of wages is the major contributor. In a particular retrospective study by Yawn et al., which included 1810 families, it was determined that the average parental work loss was three hours per episode per affected child. Although the generalization of this study is limited by its main population of non-Hispanic whites with a higher income and education than the national average, it still provides valuable comparative data. In the study, parents who reported missing work due to an episode of otitis media in one of their children usually reported work losses of 0.5 to 1 day, related to short periods for physician visits or to care for the child during the most distressing part of the illness. In addition to loss of wages, the families made special child care arrangements (other than the usual day care or
babysitter) for another 141 days. Multiplying these numbers times the incidence of otitis media accentuates the impact of the disease on the society.

Stool and Field determined that the impact of recurrent otitis media on families can be categorized as stresses, attitudes, and financial considerations. Stresses include upsetting the usual patterns of family interactions and functioning, putting an increased burden on mothers to care for children, detracting attention from other siblings, and possibly decreasing the sick child’s ability to respond to stimulation. Changes in attitudes entails increased worry about continued problems with the child, increased concern about possible delays in the child’s development, decreased sense of parental control and competence in the care of their children, and strain regarding trust and credibility with health care providers. Finally, the financial considerations highlighted encompass increased subsidiary costs including transportation and parking for healthcare appointments and adequate or inadequate insurance coverage. Unlike Yawn and colleagues, Stool and Field estimate parental absence from work at 2 days. This would translate to three hundred to six hundred million dollars per year in lost wages not including lost work productivity. The impact on families alone provides incentive to pursue cost-effective options in medical management.

By looking at medical expenditures, which include provider visits, medications, and possibly surgery, the continued impact on family and society can be assessed. In the United States, two to four billion dollars may be spent on medical and surgical treatment of otitis media each year depending upon how many children receive care for acute or recurrent otitis media. In a study that looked at the trends in antimicrobial drug prescribing by office based physicians in the United States during 1980, 1985, 1989 and
1992, it was determined that the use of older antimicrobials, such as penicillins (including ampicillin) declined in favor of newer, more expensive drugs, such as amoxicillin, and more expensive and broader spectrum drugs, such as cephalosporins. These findings are similar to findings recorded in Northern Ireland during 1983-1987. This implies that worldwide a large part of the healthcare dollar is being spent on drugs.

Surgery has also been on the rise. About a million children a year undergo myringotomy, with or without ventilatory tubes, making it the most frequent childhood minor surgery performed under general anesthesia. This trend is also seen in other parts of the world. In the United Kingdom since 1967, the rate of myringotomy has increased 211% by the early Nineteen-eighties. Croteau and colleagues concluded that in comparing the trends in surgical intervention and the rates of medical consultation for otitis media in the early eighties, the increase in surgery rates are related to a higher frequency of otitis media rather than an aggressive pattern of treatment.

In 1996 alone, estimates of resource use for chronic otitis media and eustachian disorders translated to 13,187 inpatient hospital days, 13,474 hospital ambulatory surgery days, 212,667 hospital outpatient encounters, 2,842,732 physician office encounters, 466,240 emergency department encounters and 5,000,644 ordered medications. In looking at this in dollars the national surveys in 1994 put the figures at $1881 per discharge and inpatient days, $95 per office based physician encounters and prescriptions, $547 for hospital outpatient encounters and prescriptions, $547 per free-standing ambulatory surgery center encounter, $350 for emergency department services, and $32 for outpatient medications. With the continued rise in the national healthcare
costs, it can be assumed that costs for diagnosis and treatment of otitis media has increased during the latter half of the nineties as well.

In order to reduce the burden on families, physicians, and third party payers, several studies have been performed to determine the most cost-effective treatment methods. A prospective study in 1993 looked at the costs associated with medical treatment with amoxicillin/clavulanate and cefpodoxime proxetil in the treatment of acute otitis media. The study determined that the total associated costs were greater for amoxicillin/clavulanate therapy. In addition, the time that parents had to deal with treatment failures or side effects was also greater in this group. Interestingly, amoxicillin continues to be the favorite prescription for AOM in the United States.

A second study looked at four different treatment interventions for persistent middle ear effusion. The results determined that the most cost effective intervention combination is corticosteroid plus antibiotic at the visit six weeks after the initial diagnosis, followed by a second antibiotic in non-responders at visit 2 (9 weeks after AOM diagnosis), and referral for ventilating tubes in non-responders at visit 3 (12 weeks after diagnosis). The expected average expenditures per case wages to clear bilateral middle ear effusion for the fore mentioned intervention without parental travel or lost wages would be $600.91 based on reimbursement of Colorado private practice charges and $350.27 based on Colorado Medicaid reimbursement. Stool and Field indicate that a simple cost effective model can be utilized to compare two alternative methods of treatment for recurrent otitis media: antibiotic treatment verses surgery. The model considered each element that makes up the direct and indirect costs. Total costs of antibiotic treatment would include: initial and follow-
up visits to the provider, cost of antibiotics, cost of decongestant, hearing and/or tympanometry testing, transportation costs, lost wages, and child care costs. While the surgery model would contain hospital charges, other costs associated with surgery including professional fees of surgeon and anesthesiologist, laboratory tests, hearing evaluations, days lost from work and associated child care days. Based on this analysis, surgery provides the most cost-effective model because the outcome reduces otitis media with effusion by one month. Medical therapy consumes more of the healthcare dollar than surgical therapy even though the cost-utility ratio of surgical therapy is lower than for medical therapy. Although this analysis presents evidence that surgery may be more cost-effective than prophylactic antibiotics, it is not realistic. To prescribe surgery upon the initial diagnosis of AOM could result in potential resource waste for children who are not chronic. Surgical management of otitis media with effusion is a cost effective option for children with severe and recurrent OME that fails to respond to medical therapy.

Most researchers believe the most cost-effective treatment for otitis media with effusion would be a vaccine for acute otitis media. This is theorized because vaccines have proven highly effective when applied to large populations and have resulted in significant benefits. To reduce the number of potential cases even by 1% would greatly lower the resources (the two to four billion dollars) spent on treating OM in the United States alone. The difficulty in developing a vaccine for AOM is that a wide variety of viruses or bacteria can cause the disease. Because most acute otitis media cases are caused by a greater variety of pneumococcal serotypes than are most invasive infections, current candidate vaccines may only potentially prevent 65% of middle ear infections. AOM cannot be eliminated by vaccine alone due to the number of organisms that can
cause the disease.

Conclusions

Otitis media is a disease of infancy and early childhood with approximately thirty million cases being diagnosed yearly in the United States. Treatment modalities prescribed by American physicians are applied sequentially with the initial intervention consisting of antibiotics, followed by considerations towards immunizations, and finally surgery when other methods have failed. As a result, the cost consequences include physician visits, medications, surgery, parental lost wages, and increased childcare costs. In the United States alone, this can equate to three and a half billion dollars annually.

As evident by the amount of research that has been performed, the high incidence of otitis media in children is a public health concern. The burden of illness affects not only the children inflicted with the illness, but society in general. Providers, third party payers, and parents feel the consequences of the disease through multiple medical visits and lost wages. A major step toward reducing the incidence of otitis media can and should be achieved by minimizing infant exposure to the identified risk factors. If the risks are unavoidable, medical treatment of the disease is advised as a principal treatment method. Observation may lead to unnecessary complications due to the inability to predict which children will have spontaneous resolution of AOM. In regards to the most cost-effective method of treatment, a vaccine applied to high-risk children may minimize the disease in a high number of potential cases. Elimination of the disease is not possible due to the number of bacteria and viruses that result in AOM. Reduction of the burden of illness on society can be obtained by further introduction of medical treatments by the pharmaceutical industry.
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