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***Parent and Physician Decision Making  
in Children with Suspected Ear Infection***

***Presenting to a  
Children's Hospital Emergency Department***

by



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Thesis submitted to  
the School of Graduate Studies and Research  
in partial fulfillment of the requirements for the  
MSc degree in Epidemiology

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## ABSTRACT

***Problem Statement:*** This study examines the parent decision to consult a physician, a physician diagnostic decision and a treatment decision in a common childhood illness, acute otitis media (AOM).

***Method:*** Physicians and parents of children with suspected ear infection consulting an emergency department in March-June 1998 were surveyed to describe factors related to parent and physician diagnostic and treatment decisions.

***Results:*** Parents consulted the ED when their usual caregiver was unavailable. Thirty-eight percent of 769 children were diagnosed with AOM. Presence of earache, absence of fever, parent suspicion of ear infection, and physician work status were each significantly associated with AOM diagnosis. Antibiotics were prescribed for 78% of AOM children. Presence of earache, fever and physician work status was each significantly associated with a decision to prescribe antibiotics.

***Conclusion:*** This study provides information to support the development of a physician-parent guide to the diagnosis and treatment of AOM.

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## **List of Abbreviations**

|             |   |
|-------------|---|
| <b>AOM</b>  | <b>Acute Otitis Media</b>                     |
| <b>ED</b>   | <b>Emergency Department</b>                   |
| <b>CHEO</b> | <b>Children's Hospital of Eastern Ontario</b> |
| <b>OI</b>   | <b>Other Illness</b>                          |
| <b>URTI</b> | <b>Upper Respiratory Tract Infection</b>      |
| <b>TM</b>   | <b>Tympanic Membrane</b>                      |
| <b>Ab</b>   | <b>Antibiotic Therapy</b>                     |
| <b>WW</b>   | <b>Watch and Wait</b>                         |
| <b>LR</b>   | <b>Logistic Regression</b>                    |
| <b>OR</b>   | <b>Odds Ratio</b>                             |
| <b>CI</b>   | <b>95% Confidence Interval</b>                |
| <b>IQR</b>  | <b>Inter-quartile Range</b>                   |
| <b>MD</b>   | <b>Medical Doctor</b>                         |

## CHAPTER 1

Every medical encounter in a pediatric emergency department (ED) consists of three decisions: 1) a decision by the parent to seek medical consultation; 2) a physician diagnostic decision and 3) a physician treatment decision. What factors contribute to the parent and physician decisions in the context of acute childhood illness? What are the outcomes to the child and health care system as a result of these decisions?

### *1.1 Introduction*

This study addresses these broad questions within the context of a prevalent, acute but not life-threatening childhood illness, acute otitis media (AOM). In Canada, AOM is one of the most commonly diagnosed childhood diseases, with approximately eighty percent of all children having experienced at least one episode by the age of three years<sup>1-2</sup>. At a 1998 symposium on diagnostic criteria of this disease, AOM was defined as “middle ear effusion (fluid) and recent onset of signs and symptoms of acute local or systemic disease”<sup>3</sup>. The disease places a tremendous burden on children and parents. In the short term, its impact may be felt by the child as severe ear pain, sleep and feeding disturbance and interference with day care or school attendance and by the family as parental worry and sleep and work disruption. In the long term, AOM may adversely affect the child’s hearing, with negative effects on the development of speech and language<sup>5</sup>. Recurrence of the disease is common, with some children experiencing multiple episodes annually. AOM also places a huge burden on the health care system<sup>3, 4, 6</sup>. AOM is the most common childhood diagnosis made in office practice<sup>2</sup>. Diagnosis and treatment of this illness alone accounts for approximately 40% of all community physician office visits for symptoms of upper respiratory tract infections and 23% of all office visits, annually<sup>2</sup>. AOM diagnoses account for approximately 6% of all annual

patient visits to pediatric emergency care facilities<sup>7</sup>. The treatment of AOM accounts for approximately half of all outpatient antibiotic prescriptions for young children<sup>2, 3,4,6</sup>.

Despite its prevalence and considerable burden on the child, family and community, controversy exists in the medical community as to the diagnosis and optimal management of this childhood illness. There is little consensus regarding what constitutes a clinical diagnosis of AOM<sup>2, 8-14</sup>. A typical decision-making situation is one in which a parent brings an infant or toddler, crying and acutely ill with symptoms of ear pain or ear tugging, fever, irritability, sleep disturbance, and /or upper respiratory illness to a physician for medical diagnosis and symptom management. A number of factors may influence the parent's decision to seek medical advice, including a perception that the child is at risk of serious complications and a perception that the parent is no longer able to manage the symptoms of the illness. A busy physician listens to the parents' version of the child's problem, formulates a mental representation of the decision task, and generates hypotheses as to the etiology of the presenting problem. The physician then performs a physical examination of the child in an attempt to confirm or refute the hypothesized diagnoses. The examination may include visualization of the middle ear with an otoscope, in itself a difficult, somewhat subjective task. The physician's subjective interpretation of the condition of the tympanic membrane, in comparison to his mental image of a normal condition, serves as his diagnostic standard. Although objective diagnostic standards, such as acoustic reflectometry and tympanometry, do exist, these are rarely used in routine clinical practice<sup>14</sup>. Tympanostomy and culture of middle ear fluid, the diagnostic "gold standard", is invasive and time-consuming and not feasible in most ED settings. The medical literature offers limited diagnostic guidance. A review of 43 published research reports on AOM spanning a 24-year period noted that only half described any diagnostic criteria for the disease<sup>9</sup>. A 1990 survey of 165 American physicians generated 147 different sets of criteria<sup>15</sup>. Clinical leaders

have proposed that AOM is over-diagnosed, given its high incidence relative to other acute childhood illness and the lack of uniform diagnostic criteria<sup>16-19</sup>. They have called for a reexamination of the diagnostic criteria used to classify this illness. Nonetheless, the examining physician must make a diagnosis based on her interpretation of the child's condition in light of her own knowledge and experience with the disease.

Following a somewhat subjective diagnosis, the physician must make a recommendation about treatment in a particular clinical situation. This decision is one of immediate antibiotic therapy or watchful waiting. Again, the scientific community is divided over the optimal treatment choice in AOM<sup>16-20</sup>, though antibiotic therapy has traditionally been the preferred treatment. Variation in antibiotic prescribing rates across physician groups and countries reflect the lack of consensus in the literature. Froom<sup>21</sup> found that the proportion of diagnosed cases treated with immediate antibiotic therapy ranged from 30% to 97% in an international survey of family physicians. Previous experience with the disease, physician awareness and interpretation of the scientific literature, individual attitude to risk-taking, responsiveness to parental preferences, and awareness and adherence to professional treatment guidelines all likely factor into the physician treatment decision for the individual child in the clinical situation<sup>22,23</sup>. The examining physician intuitively calculates the probability of clinical improvement with different treatment options for this particular child, and makes a treatment decision.

In Canada, there is little epidemiological surveillance of AOM treatment. In the only Canadian study to date, Pennie<sup>2</sup> reported the frequency with which children less than 16 years were prescribed antibiotics for AOM in primary care. Ten outpatient practices (5 family, 3 pediatric, and 2 urgent care centers) in southwestern urban Ontario were monitored during February and March 1997. AOM was diagnosed in 927 of 2467 visits for acute respiratory illness (38%). Immediate

antibiotics were prescribed in 901(97%) of these children; 94% of the prescriptions were for a 10-day duration. Nineteen (2%) children diagnosed with AOM were given a prescription for antibiotics to be filled if the child did not improve. Only 7 of 927 (1%) were given analgesia alone. Antibiotic therapy for AOM accounted for 53% of all antibiotic prescriptions (920/1706). The group of urgent care physicians was 28% more likely than the group of pediatricians (OR 1.28 [95% CI 1.04-1.58]) and 54% more likely than the group of family physicians (OR 1.58[1.1-2.1]) to prescribe immediate antibiotic therapy. This group was also more likely than the others were to disregard guidelines when selecting antibiotics for uncomplicated AOM. Specific factors contributing to the diagnostic and treatment decisions were not investigated. The degree to which parents adhered to different treatment recommendations and the outcomes of these diagnostic and treatment decisions were also not investigated.

Medical and surgical treatment of children with middle ear infections constitutes a major segment of health care expenditure for illness in children. Alsarraf<sup>24</sup> proposed that the average direct cost of AOM is about \$100 US ([ $\$1/\text{day drug cost}$ ], [ $\$35 \text{ per physician visit}$ ] based on the assumptions that the average case receives 1.5 courses of an antibiotic agent and 2.5 physician visits). The average indirect cost was estimated at \$133 (based on a loss of one half-day of work [ $\$43$ ] plus travel [ $\$10$ ] for each physician visit). The average total cost, therefore, of a diagnosed case of AOM was assessed as \$233 (1996 US dollars). This may be a conservative estimate, given that more expensive antibiotic agents are sometimes used and for longer duration. Projecting these costs on a caseload of 14 million American children under the age of 5 years yields a total annual expenditure of 3.3 billion dollars for care of AOM annually. Canadian AOM annual expenditures have been quoted as 300 million dollars<sup>25</sup>. Physicians are often consulted to manage children with suspected AOM or viral illness when the clinical presentation does not allow a differentiation between viral

and bacterial etiology. In these cases, it is not clear whether or not antibiotic therapy is required. Clearly the implications to the child, family and community are great if the antibiotic prescribing decision could be tailored to those children truly requiring this therapy.

The main objective of this study was to provide information about parent and physician decision making in the context of AOM in a ED setting. Its ultimate goal was to provide important baseline information in order to conduct a randomized controlled equivalency trial comparing antibiotic and expectant treatment options, and to develop a physician and parent information guideline on the diagnosis and treatment of AOM in this children's hospital ED.

## **1.2. Review of the Literature**

### ***1.2.1. The Parent Decision to Seek Medical Consultation in the Emergency Department***

#### ***1.2.1.1. Parent Judgment of the Nature and Threat of the Illness***

There is some evidence to suggest that parents may be more effective than health professionals in the early identification of illness in their children<sup>28</sup>. Some parents intuitively identify subtle changes in their children's behavior that, with time, progress to significant overt illness. The decision to consult a physician varies among parents, and is mediated by parents' interpretation of the meaning and potential threat of the suspected illness to their child's well being, and their appraisal of their ability to manage the illness<sup>28</sup>. When asked why they are bringing their child to a physician, most parents state that they are seeking a diagnosis (or explanation) and/or reassurance that the illness is not serious, and assistance with symptom management<sup>26-31</sup>.

Investigators<sup>26-31</sup> have explored parents' interpretation of the potential threat posed by symptoms of fever and pain at the time of medical consultation. The purpose of these studies was to identify what symptoms generated parental concern, and to evaluate the degree of congruence between parent and physician regarding the potential threat posed by these concerns. These papers emphasize that health-seeking behavior is influenced by the parents' *subjective perception* of the significance of the clinical symptom in relation to both its potential to cause harm and in their ability to manage the symptom. The subjective perception may have little congruence with objective reality. Instead, parent interpretations may be colored by personal experiences with similar symptoms in this child or other children, or experiences of friends and family or others depicted in the lay literature or mass media. Kramer<sup>26</sup> and colleagues surveyed a convenience sample of 202

Canadian parents of febrile toddlers about their knowledge, attitudes and fears concerning fever and its treatment at the time of medical consultation. Parents were found to hold misconceptions about the definition of fever, its possible complications and potential threat to the child's well being, and appropriate management strategies. Half of the parents labeled a temperature < 38 degrees Celsius as a fever, 43% thought a temperature < 40 degrees C was dangerous, and 15% believed that, if left untreated, a temperature would inevitably rise to 42 degrees C. Despite these beliefs, parents' minimal threshold for concern for their own child rose in concert with a rising temperature. This suggested that they readjusted their cut-off point upward as the symptoms intensified. Most parents were judged as overly aggressive in their treatment of a fever. The beliefs about the definition and potential complications of fever did not differ by socioeconomic class. The researchers concluded that undue fear and over treatment were widespread among parents of infants and young children in this sample. They labeled the phenomenon "fever phobia", and called for education of parents regarding the definition and appropriate treatment of fever. Clearly parents interpretation of the fever, whether medically correct or not, influences their health seeking behavior. If parents are concerned about what they perceive as fever, they are likely to seek medical advice and/or guidance regarding diagnosis and treatment.

Similarly, Wyke <sup>27</sup> and colleagues surveyed a random sample of British parents of 234 children presenting to their family doctor with symptoms of upper respiratory tract infection and cough. In a logistic regression model, they found that a physician was most likely to be consulted if the parent believed the child had severe symptoms or if the symptoms affected the child's daily behavior. No social characteristic had a significant

influence on the decision to consult the physician over and above the influence of the characteristics and effect of the symptoms itself. The investigators concluded that most parents based their consulting decision on their assessment of the severity of their child's symptoms.

Kai <sup>28</sup> explored the relationship between parent concerns and health-seeking behavior. Ninety-five consecutive parents presenting to the health authority for treatment of their preschool children with acute respiratory illness participated in individual or focus group interviews designed to elicit the nature of their concerns and reasons motivating their medical consultation. The interview data suggested that a child's symptom was identified as a cause for concern if the parent believed it posed a threat to the child's well-being, if its continued presence signified serious illness, or if it posed a future potential threat to the child's well-being. In this sample, symptoms of fever and cough were identified as sources of concern. If the parent or lay support network was unable to interpret the meaning of the symptom, the parent was more likely to register concern and seek medical evaluation. Also, if the parent believed that the symptom signified worsening health status, or the potential for a rapid deterioration in condition, the parent was more likely to exhibit anxiety and seek health care guidance. Parent beliefs about the potential for harm associated with a symptom was influenced by previous experience, lay support guidance, and external influences (i.e. mass media). If the parent felt that they could not manage the symptoms (i.e. return the child to usual state of wellness, or prevent further deterioration in the child's condition), the level of anxiety and concern increased, and the parent was again more likely to seek health care advice. If lay supports, i.e. family and or friends, were unable to offer health care strategies, or provide physical assistance, a parent was

more likely to seek health advice. Kai <sup>25</sup> proposed that two fundamental factors influenced parents' concerns about their child's symptoms:

- The subjective interpretation of the degree of threat to the child's well-being
- The perception of their ability to manage the illness

Hansen <sup>29</sup> surveyed a random sample of 1982 Danish families with children under the age of 8 years to identify which childhood illnesses were perceived as particularly stressful. Acute otitis media was one of four illnesses consistently identified as a source of family stress. The threat of the illness to the child's health, particularly when the parents had no previous experience with the illness, was the primary correlate of the stress.

#### *1.2.1.2. Access and Availability of Health Care Resources*

Some parents consult a children's hospital ED for medical diagnosis and treatment when their own physician is not available and they believe urgent care is required<sup>32, 33</sup>. Some parents select a pediatric facility over a general hospital facility because they believe that the care will be more "child-focused". Other parents present to the ED on the recommendation of their own physician, either following a medical visit or telephone consultation<sup>32, 33</sup>. In communities in which the hospital ED operates a telephone advice line, a number of parents may present on the recommendation of the nurse staffing the advice line. Oberlander <sup>33</sup> reported that those parents who sought advice from alternate sources (i.e., other family members, friends or telephone line) prior to the ED were more likely to use the department appropriately than those parents who presented when no prior advice was sought. This suggests that other family members or friends may serve as "lay physicians" by helping the parent interpret the meaning of the illness, identifying some alternate care strategies, and manage the child's symptoms or illness. In addition,

consultation with other health professionals may serve as a filter to determine which parents require emergency care for their children.

Some parents use an ED like a family doctor's office, either because they have no family doctor, or find the department convenient or more focused on the health needs of children<sup>32</sup>. Over half of parents consulting a community hospital ED in the United States did not have a family physician<sup>34</sup>. Canadian statistics are not available. Among those American parents who do have a family doctor, cost considerations influence the decision to consult a ED. Although cost issues may not be as salient in the Canadian context, patterns of health seeking behavior based on convenience or lack of access to other sources must be considered.

*In summary*, parents inevitably worry about their children when they are ill. Not unexpectedly, factors that may influence parents' decision to seek medical assistance for their child include:

- Child's symptoms
- Parent's judgment of the nature of the problem
- Parent's evaluation of their ability to manage the illness
- Availability and access to health care resources

### ***1.2.2. The Physician Diagnostic Decision***

Medical decision making occurs in the context of *uncertainty*. In every clinical encounter, a physician must classify a child's signs and symptoms as one of several possible diagnostic entities, based on the available evidence. Diagnostic decision making requires that information be *gathered* from a variety of sources (e.g. parent or child history, physical examination); the various items of information be weighted for their relative importance and accuracy (*evaluation*), and the weighted information be integrated into some overall judgment (*logical inference*)<sup>35</sup>.

The physician faces potential challenges at each of these three stages of diagnostic decision making. *Gathering data* is more complicated than simply conducting a physical examination. 'Marshalling all the facts' may produce a mountain of data leading to confusion rather than clarity. The physician must possess knowledge about the relative likelihood of different competing diagnoses given the presence or absence of particular clinical signs and symptoms in the practice population<sup>35</sup>. An initial set of hypothesized diagnoses enables the physician to prioritize what data is subsequently gathered. Knowledge of clinical correlates that accurately discriminate probable from plausible diseases in the clinical situation, coupled with the relative prevalence of these diseases in the population serve to stimulate the gathering of relevant versus confusing information. Data gathering leads to a narrowing of the diagnostic possibilities and further data gathering in an iterative process. The physician's skills in communication and examination of the patient are critical to the data gathering process<sup>35</sup>. Once the relevant data is gathered, it must be combined in a process that involves differentially *weighting each item* according to its ability to confirm or refute possible diagnoses. This process involves dealing with *probabilities* (a particular diagnostic sign has only a probabilistic relationship to a diagnosis) and may entail an explicit calculation, or more commonly, be conducted intuitively on

the basis of combined knowledge and experience<sup>35</sup>. Next, the list of possible diagnostic categories must be evaluated in the light of the evaluated evidence, and finally a diagnostic label assigned to the child.

### ***1.2.2.1. Factors contributing to a Physician Diagnosis of AOM***

#### ***a) Interpretation of Clinical Signs and Symptoms***

There is little consensus in the medical community on how to establish a diagnosis of AOM<sup>3</sup>. The 1998 symposium published a definition of AOM that required the presence of symptoms of acute local or systemic illness. Most medical writings include various combinations of patient-reported symptoms and physical signs in definitions of AOM<sup>8-12</sup> e.g., fever, ear pain, ear pulling, sleep disturbance, irritability and history of recent upper respiratory tract infection. However, there appears to be little agreement as to what clinical signs or symptoms, if any are critical to the diagnosis of AOM<sup>3-14</sup>.

Many of the purported associations between clinical signs and symptoms and AOM disease were generated in the original treatment trials of AOM. There was no “gold” diagnostic standard to confirm the presence of disease. Symptoms were retrospectively assessed following a clinical diagnosis of AOM. The relative frequency of these signs in the population at large, and in association with other common childhood respiratory illnesses, was not considered. Clinicians now recognize that the symptoms of upper viral illness; e.g., fever, irritability and sleep disturbance; may mimic those associated with AOM, and question how best to differentiate these diagnoses on the basis of clinical signs alone. Difficulties in establishing the presence of clinical signs and symptoms in the pediatric population also contribute to the diagnostic difficulty. In some cases, the physician must rely on his or the parents’ subjective interpretation of the child’s behavioral cues e.g. presence of ear pulling. Even earache, assumed to be most predictive of

AOM, may be of limited value in preverbal children. Physician surveys have also demonstrated variation in the definition of common childhood signs of illness, such as fever, irritability and ear pulling or ear rubbing. Ipp and Jaffe <sup>36</sup> surveyed 73 family physicians and 24 pediatricians to ascertain their knowledge and attitude regarding fever and its management in children under 2 years of age. They noted a discrepancy in both the definitions of fever and its likely complications. More confusion exists around the definition of ear pulling or ear rubbing.

In an attempt to define signs and symptoms diagnostic of AOM, Niemela and colleagues <sup>37</sup> recorded the presenting clinical signs and symptoms of a cohort of Finnish children (N=354) whose parents voluntarily consulted a pediatrician, otolaryngologist or general practitioner during a one month period in 1993. A diagnosis of AOM was based on the physician otoscopic examination. There was no assessment of the degree of diagnostic agreement among the three study physicians or bacteriologic confirmation of the diagnosis with tympanocentesis and culture. One may question the degree of consistency in assessment and interpretation between an otolaryngologist and general practitioner. The clinical signs and symptoms of children diagnosed with AOM (N=190) were compared to those classified with upper respiratory tract illness [URTI] (N=164). Univariate analyses showed that the presence of ear-related symptoms; e.g., earache (OR 5.4 [95%CI 3.3-8.9]), rubbing of the ear (OR 5.0 [2.9-8.6]) or feeling of blocked ear (OR 4.5 [1.3-16]); were each associated with a diagnosis of AOM, regardless of age. Although 78% of children with ear-related symptoms were diagnosed with AOM, 32% of children  $\leq$  2 years and 20% of children over 2 years exhibited no ear-related symptoms. Rhinitis (OR 2.3 [1.2-4.1]) and excessive crying (OR 3.0 [1.6-5.8]) each increased the likelihood of AOM in children older than 2 years of age. The presence of sore throat (OR 0.5[0.3-0.9]) and fever (OR 0.5[0.3-0.9]), both mainly noted in children over 2 years of age, were associated with URTI.

Symptoms significantly associated with a diagnosis of AOM in univariate analyses were entered into a forward stepwise logistic regression model to predict the diagnosis of AOM. The presence of rhinitis, excessive crying, earache, ear rubbing and feeling of blocked ear together correctly classified 74% of the entire cohort. The presence of cough, headache and conjunctivitis were negatively associated with the presence of AOM. For children under 2 years of age, the combination of rhinitis, earache and ear rubbing correctly classified 77% of the children diagnosed with AOM. In children 2 or more years old, earache, excessive crying and feeling of blocked ear correctly classified 72% of the children diagnosed with AOM. The study is difficult to replicate and its findings difficult to incorporate into clinical practice because the investigators failed to objectively define many of the clinical symptoms examined, such as ear rubbing, excessive crying, feeling of blocked ear, and fever. No objective diagnostic standard was used to confirm the clinical diagnosis.

Kontiokari <sup>38</sup> examined the relationship between symptoms and AOM diagnosis in a cohort of 138 healthy preschool children attending day care. Earache increased the likelihood of AOM diagnosis by a factor of 21 [95% CI 7-106]. Sore throat (OR 3.2[1.1-11]), sleep disturbance (OR 2.6[1.1-6.9]) and fever (OR 1.8[1.1-3.2]) all independently increased the likelihood of AOM. Symptoms of earache and sleep disturbance together correctly classified 71% of the AOM diagnoses in a logistic regression model. The large confidence intervals suggest that the number of children with the outcome of interest may have been inadequate for the analysis.

#### *b) Interpretation of Otosopic Findings*

Otosopic evaluation of the middle ear is considered a critical component of the diagnostic process in AOM <sup>5,7-11</sup>. The diagnosis of AOM depends on the presence of middle ear fluid. Textbook definitions of otoscopic criteria generally include erythema and/or exudate and/or

tympanic membrane bulging and/or immobility assessed with pneumatic otoscopy<sup>8</sup>. However, otoscopic diagnostic criteria are not standardized, and their evaluation is subjective. The equipment used, the willingness of the child to be examined, the manual skill of the physician, and knowledge of the presenting symptoms influence the subjective interpretation of the otoscopic examination. Wallsten<sup>39</sup> showed that physicians tend to subjectively distort information gathered in the latter part of a diagnostic work-up to support their diagnostic opinion formed up to that point in the examination. Other tools considered potentially more reliable and valid than standard otoscopy (less operator dependent), such as pneumatic otoscopy, tympanometry and tympanocentesis and culture, are not widely used in clinical practice<sup>3, 13, 14</sup>. Tympanometry provides an indication of the presence of fluid in the middle ear with an approximate sensitivity of 90% and specificity of 77%<sup>14</sup>. It does not inform the physician as to the composition of the fluid (e.g. containing bacteria or sterile). Tympanocentesis and culture, the only diagnostic procedure that provides information about the nature of the fluid in the middle ear, is invasive and time-consuming and therefore not a useful assessment tool in an ED setting<sup>14</sup>.

As with clinical signs and symptoms, otoscopy findings in AOM may overlap with those in other diseases and conditions. The presence of erythema can signify not only the presence of a bacterial infection but also viral upper respiratory infection or simply crying associated with the examination. Several studies have surveyed physicians to determine AOM otoscopic diagnostic criteria<sup>12-13</sup>. These studies noted that the presence of a bulging TM was consistently reported as a diagnostic criterion. However, these written judgements may reflect textbook knowledge rather than clinical practice criteria. The inter-rater agreement in subjective interpretation of otoscopic

criteria among physician groups, e.g., ED physicians, otolaryngologists, pediatricians, and family physicians has not been measured.

***c) Knowledge of Risk Factors, and Prevalence of Disease in the Study Population***

The prevalence of a target disease in a clinical population affects diagnostic decision making<sup>35</sup>. The more often a clinical symptom and/or sign is associated with a diagnosis, and the more prevalent a diagnosis is rendered in a clinical setting, the more often a symptom/sign will generate that clinical diagnosis in future similar clinical situations. A clinical history and examination that directs a physician to expect to see AOM will narrow the list of initial alternate hypotheses considered and may restrict the subsequent data gathering to that which serves to confirm or refute AOM. This follows from Bayes theorem<sup>40</sup>, that states that the conditional probability that a child is suffering from a hypothesized illness (AOM) given a positive diagnostic procedure (bulging TM on otoscopy, ear pain on exam) [posterior probability] is a function of P(H), the prevalence of the hypothesized disease (prior probability), the conditional probability of a positive procedure given that the patient actually has the hypothesized disease, P(Proc.+/H), and the prevalence and conditional probabilities of the alternative hypothesis (e.g. TM bulging and/or ear pain in viral upper respiratory tract illness).

In its simplest form, Bayes' formula<sup>40</sup> states that:

$$P(H/Proc.+)= \frac{P(H) \times P(Proc.+/H)}{P(H) \times P(Proc.+/H) + P(Alt.H) \times P(Proc.+/Alt.H)}$$

Where H is the hypothesis being evaluated, Proc.+ is the probability of a positive diagnostic procedure, and Alt. H is the probability of an alternative hypothesis. This last probability is included because Bayesian thinking always involves contrasting a hypothesis with one or more

alternative hypotheses. These alternative hypotheses can be either another diagnosis or no disease.

Population-based studies report that AOM is diagnosed most frequently in children under the age of 3 years, in males, and during the late fall and winter months<sup>1,4,84-85</sup>. Therefore, a male toddler presenting in the winter months with physical symptoms compatible with AOM and upper respiratory viral infection may be more likely to be diagnosed with AOM, given the physician's knowledge of the age-specific prevalence and seasonal distribution of the disease. In contrast, during the summer months when other infectious diseases are more common, the diagnostic label attributed to identical clinical symptoms is likely an upper respiratory viral infection. Although Bayes' formula represents the accepted normative methods for revising probabilities, psychological research has shown that most people do not intuitively make decisions in such a calculated manner. Rather than explicitly computing the probability of disease given the prevalence of different diseases and the clinical findings, physicians' diagnostic decisions tend to be influenced by rules of thumb or "judgment heuristics" acquired through experience in the setting<sup>35</sup>. Although generally helpful, these judgment heuristics may introduce bias (distortion) into the decision-making process. These rules of thumb include the representativeness heuristic ["what's common is most likely"] and the availability heuristic ["these symptoms remind me of the case I just saw, therefore it's probably the same diagnosis"]. As an example, the same physician examining different children presenting with similar symptoms may classify these children with the same diagnostic label, whereas a different physician examining the same children would assign a consistently different label, regardless of the actual prevalence of the different diseases in the population.

The prevalence of diagnosis of a particular disease is affected by the setting. If children do not present to the study site for evaluation, they will not be entered into the diagnostic database of the clinicians in that site. The physicians providing clinical service in a particular health care setting formulate diagnostic criteria based on the child population served, regardless of the degree to which this may be truly representative of the spectrum of disease<sup>35</sup>. Children and parents presenting to an ED may systematically differ with regards to symptom presentation (nature, severity, duration) or symptom management style when compared to a cohort consulting other sources of health care, or to the cohort able to manage the illness without medical assistance. No studies have provided comparisons of cohorts in this manner.

#### ***d) Parental Diagnostic Suspicion and Treatment Expectations***

In a Finnish cohort of children presenting with clinical signs and symptoms associated with AOM, Niemela<sup>37</sup> noted that 76% of the parents correctly diagnosed their child's illness as either AOM or upper respiratory viral illness. Similarly, Kontiokari<sup>40</sup> reported that his cohort of 138 parents correctly predicted a diagnosis of AOM with a sensitivity 71%, specificity 80%, positive predictive value 51% and negative predictive value 90%. No information was given as to whether parents' diagnostic suspicions were influenced by previous experience with the illness.

Mangione-Smith<sup>41</sup> found that the physicians' perception of what treatment parents expected at the visit, rather than parents' actual treatment expectations, increased the likelihood of a bacterial diagnosis in their sample of 306 children diagnosed with AOM (OR 5.25; 95% CI 1.75-15.73]. AOM was diagnosed 49% of the time when physicians thought parents wanted antibiotics, and 13% of the time when physicians thought that the parent had no opinion about treatment (p=0.001). The actual parent treatment expectation was not significantly associated with the diagnosis. Vinson and Lutz<sup>42</sup> reported similar findings in a study of parents of children

consulting a family physician for symptoms of persistent cough. These investigators suggested that a physician might be more likely to assign a diagnosis that fulfills his perception of the parents' treatment expectations when they are less certain about the diagnosis. When the physician is more certain about the child's diagnosis, the diagnostic decision and treatment recommended are independent of the parent expectations.

#### *e) Physician Training and Experience*

The type and level of training and experience of the physician may influence the diagnostic process<sup>43-45</sup>. Physicians with more experience are assumed to generate more focused, relevant hypotheses, and gather and synthesize relevant information and determine a diagnostic label in a more succinct fashion. Experience suggests a diagnostic strategy in the same way that prior information serve to select a particular strategy. With experience, a physician may make a diagnostic decision more rapidly on the basis of the presence or absence of a select pool of "important" clinical indicators. Provided that the clinical indicators deemed diagnostic are valid, those physicians with more experience may more efficiently make valid diagnoses. However, if the clinical symptoms used are not valid indicators of disease, more experienced physicians may simply be more rapidly over- or misdiagnosing AOM. Incorrect diagnostic processes may become ingrained over time. No studies have compared the accuracy of AOM diagnosis by physician specialty or experience. However, the nature and amount of clinical information solicited and the number and range of hypotheses generated may differ depending on the level of training and specialization of the physician<sup>43-45</sup>. A physician trained in a particular specialty may be more likely to conduct a detailed search for a rare diagnosis of interest whereas a physician trained as a generalist may more likely look for the diagnosis more prevalent in the study

population. The same clinical information may be attributed a different diagnostic label depending on the differential hypotheses formulated by the physician.

### ***f) Parent-Physician Communication***

The nature of the communication between the physician and the parent/child seeking medical consultation may be an important source of uncertainty and inaccuracy in medical information<sup>46</sup>. The manner in which the physician establishes rapport with the child and parent and the nature of the parent and child interview influence the information communicated between physician and parent. Not asking the right questions or misinterpreting responses can result in erroneous diagnostic decisions on the part of the physician. The manner in which a child or parent interprets and responds to a physician's questions may be influenced by their language facility, education, trust in the health care system, and knowledge and interpretation of the meaning of symptoms and disease. A sick child generates high anxiety levels in a parent, and a sick child may not be cooperative and forthcoming with information related to his illness. The willingness of a child to submit to invasive physical examination, in the context of pain, fatigue and fear, is affected by the level of trust generated between physician and child<sup>30, 31</sup>.

A hospital ED is a fast-paced, emotionally charged environment. Parents of sick children are primarily worried about the threat of harm posed by the illness to their child's well being. Parents expect physicians to rapidly diagnose their child's problem and institute effective care to manage the illness. Timely management of their child's illness is their sole priority<sup>32-34</sup>. Physicians are committed to providing effective, efficient care within a system of triage. Fatigue and frustration stemming from long waiting times to see the doctor, coupled with the worry associated with the child's illness, may damage the communication process between parents and physician.

**In summary**, the literature suggests that the following factors may contribute to the physician diagnostic decision:

- Physician assessment and interpretation of physical signs and symptoms
- Communication between child/parent and physician
- Physician subjective interpretation of the condition of the middle ear
- Prevalence of the diagnosis in the clinical population
- Physician interpretation of the parent diagnostic suspicion
- Physician training and experience

### ***1.2.3. The Physician Antibiotic Prescribing Decision***

In medical decision making, information gathering and interpretation is a means to an end – making a treatment decision. In the context of AOM, the physician must decide between two possible treatment recommendations – immediate antibiotic therapy or recommendation of expectant management, commonly referred to as “watch and wait” (WW)<sup>16-23</sup>. In each clinical encounter, the physician weighs the relative risks and benefits of each treatment option (at least intuitively), and presents the option that maximizes the potential benefit and minimizes the potential risks to the particular child.

#### ***1.2.3.1. Factors contributing to a Physician Antibiotic Prescribing Decision in AOM***

##### ***a) Clinical Signs and Symptoms***

There is no reported data correlating particular clinical signs and symptoms to a particular treatment decision in AOM. Some clinicians suggest that the presence of ear pain, fever and a bulging, immobile TM increase the likelihood of a bacterial otitis media requiring antibiotic therapy<sup>47-49</sup>.

### ***b) Parent Treatment Preferences/Expectations***

Parents differ in their expressed treatment preferences<sup>41, 50-55</sup>. Wang<sup>50</sup> suggested the following factors affect parent treatment preferences:

- experience with the disease
- knowledge of treatment options, impressions of their effectiveness as shared by friends, work colleagues, other family members, mass media (newspaper, television, Internet)
- level of anxiety
- social obligations (e.g. no social support network to care for child or prescription needed for day care)
- cost of treatment

Anecdotal reports suggest that some parents prefer antibiotic therapy in AOM if symptom relief is expedited, regardless of its published efficacy in the diagnosed condition<sup>48</sup>. For these parents, rapid resolution of their child's pain and irritability is the most salient issue. Other parents are reticent to treat with this form of therapy, given their awareness of the emergence of and potential threat of antibiotic-resistant bacteria in the hospital and community settings.

The degree to which parents' treatment preferences influence the management decision depends on the parents' ability to communicate the preference and the relative value attributed to parental preferences by the physician. A number of studies have shown that it is not the parent treatment preference per se, but the physician perception of the parent preference that affects the physician prescribing decision<sup>41, 51-54</sup>. Barden<sup>51</sup> conducted focus group discussions with parents and physicians in an attempt to understand prescribing patterns. Physicians stated that they could safely reduce their own antibiotic prescribing, and suggested that over-prescribing of antibiotics

resulted from yielding to parental expectation. In contrast, parents indicated that they would be satisfied with the medical visit even if antibiotics were not prescribed, provided the physician explained the reasons for the decision. Bauchner<sup>52</sup> reported similar findings in a questionnaire survey of 610 randomly selected pediatricians across the United States. The report of the Antibiotic Resistance Education Project in British Columbia stated that while 48% of surveyed physicians cited parental pressure as a frequent cause of antibiotic prescribing, a similar proportion of parents felt pressure from the physician to fill an antibiotic prescription<sup>53</sup>. Parents indicated that they simply wanted reassurance that their children's condition was not serious and that they were not necessarily seeking antibiotics. A small proportion of parents requested antibiotics for their children in order that they could return to work and return their children to day care. Project co-ordinators suggested that communication between parents and physicians has probably not been adequate to correct the misperception between the two parties. Mangione-Smith<sup>41</sup> explored the extent to which parental pre-visit treatment expectations influenced physician antibiotic prescribing in two private pediatric practices in the United States. Physician perception of parental expectations for antibiotics was the only significant predictor of prescribing antibiotics in conditions of presumed viral etiology. Physicians prescribed antibiotics 62% of the time when they thought parents wanted an antibiotic compared to 7% of the time when they thought parents did not want antibiotics. There was no significant association between parents' actual treatment preference and the physician perception of the parent expectation.

Bauchner<sup>54</sup> examined parents' preferred route (oral versus intra-muscular) and duration (single dose versus 10 days) of antibiotic therapy for children diagnosed with AOM. No studies have explicitly examined parents' preferences for a watch and wait approach in comparison with

immediate antibiotic therapy. Eighty-five percent of parents of 648 children aged 3 months to 6 years expressed a preference for single-dose IM therapy. At days 3-5 after the initiation of treatment, there were no group differences in days children missed from school or day care, parental absence from work, or loss of sleep. At days 14-16, more parents with children in the IM group reported being very satisfied with the antibiotic therapy compared with parents of children in the oral therapy. Reasons for the differences in the level of satisfaction were not reported.

### *c) Diagnostic Certainty*

Gonzalez-Vallejo<sup>56</sup> explored the relationship between diagnostic certainty and physician treatment decisions. Physicians estimated the likelihood of a diagnosis of AOM in 32 hypothetical clinical scenarios. Those scenarios that elicited a high likelihood of AOM diagnosis across the physician group were considered “certain” diagnoses. Scenarios that elicited wide variation in the likelihood of an AOM diagnosis were labeled as “vague” diagnoses. Child factors, including physical symptoms and otoscopic findings, differentiated the clinical scenarios labeled certain and vague diagnoses. Diagnostic certainty tended to occur in clinical situations describing congruent information cues associated with AOM; e.g. bulging TM and ear pain; whereas diagnostic vagueness increased in the presence of two conflicting information cues believed diagnostic of AOM; e.g. bulging tympanic membrane with no ear pain. This result was validated in a post-hoc focus group discussion with a subset of the study physicians.

Seventy-five percent of the physicians indicated that they would prescribe antibiotics when their judged diagnostic certainty was  $\leq 50\%$ . Gonzalez-Vallejo<sup>56</sup> concluded that the physician sample was cautious when managing AOM, often overlooked the high rate of spontaneous recovery and

overestimated the risk of complications, and tended to prescribe antibiotics liberally whether they were uncertain of the diagnosis or as a means to treat some other disease entity.

***d) Knowledge of and Clinical Application of Scientific Evidence***

In North America, AOM is the most common childhood infection for which antibiotics are prescribed. Pennie<sup>2</sup> reported that 97% of all children diagnosed with AOM were treated with immediate antibiotic therapy in 10 community physician practices in Southwestern Ontario. Canadian rates of antibiotic prescribing for AOM diagnoses in pediatric emergency departments are not known. No national database links childhood diagnosis with medication prescriptions in Canada. High rates (>97%) of antibiotic prescribing have been recorded in national surveys of community based family physicians in the United States. The practice of antibiotic therapy in AOM is thought to have initially emerged from the treatment of pharyngitis, and become ingrained as ritualistic practice without sound evidence of its efficacy or effectiveness<sup>65</sup>. Medical textbooks and practice guidelines continue to recommend antibiotics as the first line therapy in AOM diagnoses<sup>8, 11, 66</sup>. However, there is growing controversy in the literature as to the best treatment of AOM. With the increasing prevalence of drug-resistant *Streptococcus pneumoniae* and *Haemophilus influenzae* (bacterial organisms implicated in AOM) in Canada and the United States<sup>57</sup>, medical authorities have called for more restricted use of antibiotics in AOM. Low rates (30% of all AOM diagnoses) of antibiotic prescribing in the Netherlands, with no obvious increase in the rate of serious complications, suggest that antibiotics may not be necessary in all AOM cases. The natural history of AOM is that 80% of cases will spontaneously resolve within 24 –48 hours of symptom onset. The difficulty for the physician making the treatment decision is to correctly predict which child will fail to spontaneously improve and proceed to serious complications without treatment.

The scientific literature provides little definitive guidance. Eight published double-blind, placebo-controlled randomized trials of antibiotic treatment for AOM and four meta-analyses<sup>58-62</sup> conclude that antibiotic therapy reduces the duration of acute clinical symptoms but has little impact on the resolution or recurrence of the disease. Rosenfeld<sup>62</sup> reported that AOM symptoms resolved in 24 hours for 59% of children (95% CI 53-65%) managed without antibiotics in randomized trials, rising to 87% by 2-3 days (95% CI 85-89%). Resolution was not related to diagnostic certainty. No suppurative complications occurred in either treatment group. Antibiotic therapy increased the symptom relief by 4% at 2 – 3 days (95% CI 2-7%) and overall clinical resolution by 13% at 7-14 days (95% CI 8-19%). The benefit of antibiotic therapy was more apparent when children without bacteria isolated from middle ear fluid were excluded, if bacterial eradication as opposed to clinical resolution was assessed, or if clinical outcome was assessed earlier in the course of treatment (at 2-3 days rather than 7-14 days).

Factors that have contributed to the difficulty in interpreting the scientific evidence include<sup>3, 76</sup>

- No standardized AOM diagnostic criteria across trials
- Inadequate or inconsistent statistical handling of potential confounding variables; e.g., child's age, risk exposure status, previous history of the illness, disease laterality or severity
- Inconsistent or inadequately described inclusion and exclusion criteria for study
- Poorly defined and measured outcomes, assessed by unblinded observers
- Children's adherence to the recommended treatments have not been assessed or reported
- Insufficient sample size and power to detect significant differences in adverse outcomes, i.e., mastoiditis and meningitis

- Important endpoints such as functional outcome and economic and health resource utilization costs have not been considered

The contradiction between traditional medical writings supporting antibiotic therapy and editorials warning of the growing problem with antibiotic resistant bacteria arising from overuse of antibiotics, and the indeterminate conclusions of clinical trials and meta-analyses generate a situation of clinical equipoise for the ED physician making treatment recommendations in AOM.

f) ***Physician Perspective: Relative Tradeoff of Risks and Benefits to Child and Society***

Redelmeier and Tversky<sup>63</sup> noted a discrepancy in treatment decision making depending on whether a physician assumes the perspective of the individual patient or the perspective of the broader community. Physicians tend to give more weight to the personal concerns of patients when considering them as individuals and more weight to general criteria of effectiveness when considering them as a group. The discrepancy cannot be attributed to differences in medical information. This may explain why on paper some physicians may express grave concern over the emergence of antibiotic-resistant bacteria and a willingness to recommend expectant management, yet continue to prescribe antibiotic therapy following diagnosis in the clinical situation. Physicians perceive that antibiotic resistance is a risk at a population level not at a patient level<sup>57,64</sup>. Other studies have noted that specialist physicians are more likely to institute an active intervention; e.g. prescribe a medication; than family physicians, who may be more likely to prescribe preventive care or expectant management<sup>43</sup>. These two factors may also potentially explain differences in the approach to antibiotic prescribing in the practices of tertiary level care physicians (e.g. Full time ED physician) compared to community care physicians (e.g. Office based family practitioner). Pennie<sup>2</sup> showed that pediatricians were more likely to prescribe antibiotic therapy following AOM diagnosis than family physicians in his survey.

This discrepancy between individual and group is also reflected in the judgments of lay people. Parents may be aware of the problems of “superbugs” in relation to community health, but still request antibiotic therapy for their child when he or she is ill.

***g) Standards and Guidelines endorsed by Professional Medical Associations***

There has been a concerted effort to prepare and disseminate guidelines regarding the treatment of AOM in recent years. Since 1997, the Canadian Pediatric Society<sup>65</sup>, the American Office of Health Care Policy and Research<sup>66</sup>, and the Ontario Anti-infective Guidelines<sup>67</sup> group have released consensus opinion statements endorsing antibiotic therapy as the most effective treatment in AOM. However, these scientific bodies acknowledged that their recommendations are based primarily on expert opinion rather than rigorous clinical trial evidence, and may be modified in the future. Several recent initiatives in the medical community have also attempted to increase physician awareness of the potential serious effects of the overuse or indiscriminate use of antibiotics at the individual and community level. These include the activities of the National Information Program on Antibiotics, endorsed by the Canadian Pediatric Society<sup>68</sup>. This initiative has produced a tool kit for pediatricians to use with parents. The tool kit contains information pamphlets outlining differences between bacterial and viral infections and how bacteria become resistant, non-prescription pads outlining tips on coping with a virus for children who do not require antibiotics, and compliance pads for children with bacterial infections outlining how to use antibiotics properly. In British Columbia, The Antibiotic Resistance Education Project<sup>53</sup>, co-ordinated through the Department of Family Practice at the University of British Columbia, has recommended that physicians wait 48 to 72 hours before prescribing antibiotics to treat otitis media in all children over the age of 2 years. The Canadian Pediatric

Society<sup>72</sup> consensus opinion statement cautions that 48 hour expectant management may be feasible in children over two years of age if good follow-up is assured.

In 1997, the American Health Care Policy and Research (AHCPR) office in the United States released a comprehensive, multi-media guideline (with supporting evidence in paper and electronic formats, videotape, and workshop template) on the diagnosis and treatment of chronic otitis media<sup>66</sup>. AOM was not specifically addressed in the guideline. This discrepancy may lead to treatment confusion, especially among parents, who do not differentiate the two conditions. The AHCPR is currently developing a practice guideline specific to AOM, endorsed by the American Academy of Family Physicians, Pediatrics and Otolaryngology, Head and Neck Surgery Foundation<sup>69</sup>.

#### *h) Judgment Heuristics*

The availability heuristic<sup>35, 64</sup> exerts a particularly potent influence on risk perception. The ease with which an instance of an outcome can be called to mind is affected not only by its objective frequency but also by its emotional impact. For example, media coverage can determine the perceived likelihood of a risk of complication in the patient population served in the minds of physicians as well as in the minds of parents seeking health care for their children (e.g. television, newspaper reports of flesh-eating disease, and antibiotic resistant “superbugs”). The coverage of a disease in medical journals (number of articles pertaining to a disease entity) influences physicians’ perception of the prevalence and clinical effectiveness of different treatment outcomes<sup>71-73</sup>. The occurrence of adverse effects following a treatment option can influence subsequent prescribing behavior, even though the likelihood of adverse effects is rare<sup>72</sup>. In AOM, if a physician diagnoses and treats a child with a complication of AOM, then he

is more likely to immediately prescribe antibiotics the next time he diagnoses a child with AOM, regardless of the actual risk of the complication without active treatment<sup>72</sup>.

**In summary**, the literature suggests that the following factors may contribute to the physician antibiotic prescribing decision in children diagnosed with AOM:

- Knowledge and clinical application of scientific evidence
- Parent treatment preferences, and perception of parent preferences
- Diagnostic certainty
- Physician perspective, tradeoff between relative risks and benefits to individual or society
- Standards and guidelines endorsed by professional medical associations
- Judgment Heuristics

#### ***1.2.4. Outcomes of Parent and Physician Decisions***

The status of the child's physical condition, the impact on the family, and resource use are immediate outcomes of the parent and physician decisions examined in this study.

##### ***1.2.4.1. Expected Clinical Outcome 48 hours after the ED visit***

The scientific literature indicates that clinical symptoms associated with AOM (fever, irritability, ear pain) generally resolve within 48 to 72 hours of presentation and treatment<sup>3</sup>. If symptoms continue beyond 48 to 72 hours, medical reevaluation of the child is indicated as the initial physician diagnosis and treatment recommendation may be incorrect or ineffective, or the disease may have progressed to one of several possible complications (mastoiditis, meningitis). If the physician initially prescribed antibiotic therapy, a change in antibiotic may be prudent. If expectant management was recommended, the physician may elect to prescribe antibiotic therapy. Middle ear fluid will remain visible on otoscopic examination for up to 3 months after diagnosis despite symptom resolution. This finding is not an indication for antibiotic therapy<sup>3, 13</sup>.

Although many physicians may perceive that there is little risk of adverse effects from antibiotic prescriptions relative to their potential benefit, negative effects have been well described. With certain antibiotics, gastrointestinal effects (nausea, vomiting, and diarrhea) occur in approximately 20% of treated children<sup>20</sup>. The increase in antibiotic-resistant bacteria in Canadian day care centers has been attributed to overuse and long term use of antibiotics as a treatment for AOM and its sequelae (chronic middle ear fluid). The creation of the antibiotic resistant bacteria harms the individual child and the community<sup>23-25</sup>.

Prior to the use of antibiotics, the incidence of severe complications including mastoiditis and meningitis following a diagnosis of AOM was 2 per 1000 cases<sup>73</sup>. Although randomized clinical trials and before-after studies examining the equivalency of antibiotic and expectant management of AOM have not reported these adverse events, these trials have lacked sufficient sample size and power to detect group differences in these rare outcomes. In the Netherlands, where only 30% of children with AOM receive antibiotics, the incidence of acute mastoiditis over the period 1991-1997 was recently reported as 3.9 per 100,000 cases per year. Similar figures for Canada and the United States were 1-2 per 100,000 cases per year<sup>74</sup>.

#### ***1.2.4.2. Functional Outcome***

A 1996 AOM Research Symposium<sup>75</sup> called for the evaluation of the impact of the disease on the family in terms of pain and suffering, time lost from work and other social obligations, and cost. These outcomes have not been investigated in published reports to date.

#### ***1.2.4.3. Parent Satisfaction with the diagnostic and treatment decision and decision making process in the clinical encounter***

Parents of children diagnosed with AOM are more likely to be satisfied with the diagnostic and treatment decision, regardless of its nature, when physicians explain the nature of the likely course of their illness<sup>77</sup>. The manner in which information is communicated is often as important as the content in influencing the degree of satisfaction experienced by the parent. Qualitative work has demonstrated that parents of young children with acute illness were more satisfied when physicians provided clear, adequate information about the nature and likely course of the illness<sup>28</sup>. Mangione-

Smith<sup>41</sup> and Barden<sup>51</sup> found that the manner in which the physician communicated the nature of the illness was the only significant predictor of parental satisfaction with the medical encounter. Failure to provide the expected treatment did not affect parental satisfaction.

#### ***1.2.4.4. Health care system outcomes***

The diagnosis and management of AOM accounts for almost one quarter of all childhood office visits in Canada<sup>2</sup>. However, little is known about the overall pattern of health care resource use in this illness. Reasons why parents choose to consult an urgent care center or emergency department rather than a family physician are not known<sup>77-78</sup>. The extent to which parents consult more than one health care practitioner during an illness episode is also not known. Fahey<sup>77</sup> registered concern about the potential health resource implications of unnecessary antibiotic prescribing in AOM. He suggested that, as in viral conditions such as some cases of AOM, inappropriate antibiotic use “medicalises” a self-limiting condition and increases patient expectation for physician consultation and antibiotic treatment when a similar illness episode recurs. Observational research in the UK revealed that 24% of children are re-evaluated by the same physician during a single episode of upper respiratory illness<sup>78</sup>. It seems likely that continuing to prescribe antibiotics in AOM may increase parental perceptions about the severity of the illness, and need for active treatment, and thereby influence future rates of both antibiotic prescribing and repeat medical consultations at physician offices, urgent care clinics and emergency departments.

Appendix A graphically summarizes the factors contributing to parent and physician decision making in AOM reviewed in *Section 1.2*.

## **1.3 Study Objectives**

### ***1.3.1. The Overall Objective is to:***

- increase understanding of parent and physician decision making regarding acute otitis media (AOM) , in order to provide baseline data to support the conduct of a randomized, double blind equivalency trial comparing antibiotic therapy and watchful waiting plus analgesia in AOM, and to support the development of a parent and physician guideline on the diagnosis and treatment of AOM

### ***1.3.2. The Specific Objectives are to:***

- 1) describe factors that contribute to the parent decision to consult a physician in a children's hospital emergency department (ED)
- 2) describe child, parent and physician factors that contribute to the physician diagnosis of AOM
- 3) describe the performance characteristics of a composite model and clinical score predicting physician AOM diagnosis
- 4) describe child, parent and physician factors that contribute to the physician decision to prescribe immediate antibiotic therapy following a clinical diagnosis of AOM
- 5) describe the performance characteristics of a composite model and clinical score predicting the physician antibiotic prescribing decision following a diagnosis of AOM
- 6) document outcomes of the diagnostic and antibiotic prescribing decisions to child (clinical), family (functional), and health care system (resource use)

## CHAPTER 2

### Methods

#### 2.1 *Setting*

This study was conducted in the Emergency Department (ED) of the Children's Hospital of Eastern Ontario (CHEO); a tertiary care children's hospital situated in Ottawa, Ontario, Canada. This ED provides triaged urgent care to approximately 50,000 children less than 18 years old each year<sup>7</sup>. Sixty-six percent of all children present on weekdays and 63% of all clinical visits occur between 1600 hours and 0800 hours<sup>7</sup>. Otitis media is the fourth most common clinical diagnosis, after gastroenteritis, asthma and upper respiratory infection<sup>7</sup>. In 1998-99, 2,622 (5%) children were diagnosed with AOM, and in 1997-98, 2,221 children were diagnosed with this illness<sup>7</sup>. Although no age-specific statistics are available, several department physicians estimated that 70% of children diagnosed with AOM are less than three years of age<sup>46, 47</sup>. The disease is most frequently diagnosed during the months of December through May each year. Other diagnoses of relevance to this study treated in the ED in the fiscal year 1998-99 are gastroenteritis (3889 children [8%]), upper respiratory infection (2575 children [5%]), viral illness/flu (2393 children [5%]), and fever (1203 children [2%])<sup>7</sup>.

A pediatric emergency care facility was selected as the study site because:

- Research activities are accepted practice in EDs of academic pediatric centers. Prior to initiation of this study, department staff had expressed interest in the study of children diagnosed with AOM. There had been discussions about the development of a parent decision aid to the diagnosis and management of this disease and a randomized trial to

assess the equivalency of antibiotic and expectant management <sup>90</sup>. Department registration clerks were experienced in recruitment and enrollment procedures. Role expectations included participation and facilitation of research within the department.

- Review of the number of children diagnosed with AOM suggested that accrual of a large sample of children and their parents would be feasible within a relatively short time period in the ED.
- Given the lack of funding for research assistants, daily monitoring of the number of children and parents enrolled in the study, collection of completed Parent Questionnaires, and conduct of follow-up telephone interviews was feasible in a single study site only.
- The potential participation of a neighborhood walk-in clinic and family physician office practice was explored prior to commencement of the study. Although the directors of these sites expressed interest in the research, they were not able to commit sufficient resources to ensure adequate recruitment of eligible parents and children and questionnaire administration. They also lacked computerized patient databases to track eligible but missed study children.

## ***2.2 Study Design***

This prospective study describes the contribution of selected factors to parent and physician decisions, as illustrated in Appendix A. Child, parent and physician factors were identified as potentially significant factors in the literature review.

All CHEO ED physicians were asked to complete a baseline Physician AOM Questionnaire (Appendix C) that solicited knowledge, beliefs and preferences about the diagnosis and treatment of AOM before initiation of the study.

All parents and children presenting to the CHEO ED between March 9 and June 9, 1998 were prospectively screened for eligibility at the time of registration. Registration clerks invited parents of children aged 3 months to 13 years with an ear-related chief complaint and symptoms as defined in the inclusion criteria (*Section 2.4*) to participate in the study using a standard protocol. Recruitment and enrollment protocols were posted at each registration desk. Parents consenting to participate in the study completed the Parent AOM Questionnaire (Appendix C) before a physician examined their child.

Emergency physicians completed a Clinical AOM Questionnaire (Appendix C) for all study children diagnosed with AOM upon completion of the clinical encounter. Physicians also completed a standard Emergency Medical Consultation Record for all study children.

The investigator interviewed consenting English-speaking parents by telephone 48 hours after the ED consultation (Appendix C). Parents were given the option to decline this interview at the time of study enrollment. Interviews in French were conducted by a trained study nurse.

The investigator also retrospectively reviewed all Emergency Medical Consultation Records to identify all children diagnosed with AOM during the study period. Data pertaining to each child's chief complaint, presenting symptoms, time of presentation, and physician diagnosis and treatment recommendation were extracted from the emergency record. No parent information was obtained for this retrospective cohort.

### **2.3 Study Population**

The physician population consisted of staff physicians providing clinical service in the ED (N=35). Twelve physicians with specialist training in pediatric emergency medicine

provide clinical service on a full time basis. Twenty-three physicians have training in other pediatric specialties or family medicine provide clinical service on a part-time basis. Eight additional pediatric and emergency medicine residents were unable to answer the questions on the Baseline Physician Questionnaire, so were excluded from study participation.

The parent population consisted of all English or French speaking parents of children fulfilling inclusion criteria delineated in Section 2.4 and presenting to the ED during the study period.

## ***2.4 Inclusion Criteria***

### ***2.4.1. Parent Criteria***

- Able to read English or French
- Reside in Ottawa/Carlton region

### ***2.4.2. Child Criteria***

- aged 3 months to 13 years
- ear-related chief complaint; i.e. “I think my child has an ear infection” “ear hurts”

*and one or more of the following clinical symptoms:*

- Fever defined as rectal temperature  $>38.5$  C
- Sudden onset of ear pain (within the previous 24 hours)
- Sudden onset of irritability and/or crying for no apparent reason
- Sudden onset of tugging at ear (within the previous 24 hours)
- Upper respiratory infection
- Recent onset awakening from sleep

- Acute feeding disturbance, including vomiting
- Parent suspicion of an ear infection
- Absence of ventilating tubes in middle ear.

These inclusion criteria were generated through review of AOM diagnoses recorded on Emergency Medical Consultation Records in the months of November 1997 through January 1998 and discussions with clinical experts in pediatric emergency medicine and infectious disease. Registration clerks were asked to record the number of eligible parents who declined to participate in the study and the reason for refusal on a daily basis.

## ***2.5 Data Collection Procedure***

### ***2.5.1. ED Orientation to the Study***

#### ***Physician Group***

All ED physicians were invited to an orientation session presented in conjunction with a monthly department staff meeting, at which time the investigator briefly described the aims of the study, the study protocol and specific responsibilities of the physician group. Following a question period, physicians completed the baseline questionnaire. The questionnaires were coded, and physicians were assured that their responses would be kept confidential. Other physicians were informed of the study in person or in writing, and a copy of the questionnaire was left with them to complete at their convenience. An information sheet outlining the study objectives and responsibilities of the physician group was posted on the physician research board.

#### ***Registration Clerks and Nursing Staff***

Registration clerks (N=6) were initially oriented to the study at a group meeting, and then reminded on an individual basis. All registration clerks were expected to enroll eligible

study parents and children as part of their daily responsibilities. The nursing staff was oriented to the study through nursing staff meetings, communication book notices, and poster board notices. The nursing staff had no specific study involvement.

An information sheet clearly delineating parent/child inclusion criteria, the enrollment procedure, and data collection protocol was posted at each registration desk, the triage desk bulletin board, and the department research board.

### *2.5.2. Study Monitoring*

The investigator collected completed parent and physician questionnaires daily from the registration clerk office. This ongoing investigator presence fostered an ongoing departmental awareness and interest in the study. Questions about the study were addressed as they arose. Study progress was updated on a monthly basis and posted on the ED research board and in the staff communication book. The investigator presented monthly progress reports to the nursing staff and registration clerks at their meetings. Monthly tokens of appreciation (i.e., chocolate, coffee etc.) were presented to the registration clerks and physician group.

## *2.6. Study Instruments*

Copies of the study questionnaires are in Appendix C. The relationship between the study objectives and the content of the questionnaires are tabulated in Appendix D.

### *2.6.1 Parent AOM Questionnaire*

#### *2.6.1.1. Questionnaire Development*

The Parent AOM Questionnaire was developed for this study to examine:

- Reasons parent presented for medical consultation in the ED

- Parent appraisal of the meaning of the child's clinical symptoms
- Parent assessment of their ability to manage the symptoms of their child's illness
- Types and range of health care strategies attempted by parents prior to medical consultation
- Parents' treatment expectations and/or preferences

#### *2.6.1.2. Pilot testing Questionnaire to Assess Feasibility and Content Validity*

Twenty mothers of infants and toddlers attending a day care volunteered to complete the study questionnaire. Most mothers stated that their child had been diagnosed with an ear infection in the previous year. Following completion of the questionnaire, the mothers were asked to identify questions that were unclear or difficult to answer. One mother stated that she failed to see the relevance of the question addressing education level, and refused to answer it. All the mothers stated that the questionnaire was easy to complete. The questionnaire was not modified on the basis of pilot testing of this sample.

Critical comments provided by members of the thesis committee were incorporated, and are reflected in the final version of the questionnaire in Appendix C. The questionnaire was translated into French, and then independently back-translated into English by two bilingual pediatric health care providers. The two English versions were judged comparable. It was anticipated that approximately 10% of the parents enrolled in the study would prefer to complete the study questionnaire in French.

## **2.6.2. Baseline Physician Questionnaire**

### **2.6.2.1. Questionnaire Development**

No validated physician questionnaire was available in the literature. Therefore, in order to identify salient issues around the diagnosis and management of AOM, the investigator conducted individual qualitative interviews with six pediatric specialists in emergency medicine (N=1), otolaryngology (N=2), infectious disease (N=1) and family medicine (N=2). Specific questions addressed in the interviews included:

- How do you diagnose AOM?
- What clinical symptoms raise your index of suspicion of AOM?
- What clinical symptoms must be present for you to make a diagnosis of AOM?
- How much importance do you place on your examination of the middle ear, relative to other parent or child-reported symptoms?
- Are ear findings necessary? How do you make a diagnosis if you cannot examine the ear?
- How does a child's age influence your interpretation of clinical symptoms? And your treatment decision?
- How does your assessment of a parent influence the treatment recommendations?
- How do you synthesize clinical, physical, child-related factors, and parent factors, knowledge, your clinical experience etc. when making your treatment recommendation?
- How do parent preferences for certain treatments influence your treatment decision?

This discussion generated a list of historical and clinical examination diagnostic criteria. The most frequently identified items were ear pain, fever, and the presence of a bulging tympanic membrane. The physicians commented on the difficulty in making a diagnosis of AOM, owing to a child's clinical state (often crying, irritable, won't allow physical exam) and the small anatomy as well as the subjective nature of the diagnosis. There was no consensus regarding the optimal management of AOM among the physicians interviewed. Some physicians stated that they generally prescribed antibiotics following a diagnosis of AOM, while others stated that they rarely prescribed antibiotic therapy. A proportion stated that the child's age (< or > 2 years) influenced their prescribing decision, such that they were more likely to treat a younger child with antibiotics than an older child. However, one physician stated that she was more likely to treat the older child with antibiotic therapy. Those more likely to treat the younger child stated that they were less certain about the diagnosis as assessment of the tympanic membrane is more difficult and the preverbal child cannot indicate what is wrong, and therefore more likely to err on the side of caution. The physician group also indicated that parents' treatment expectations played a role in the management decision. If parents requested antibiotics, physicians were more likely to provide a prescription when they were uncertain of the diagnosis than when parents had no treatment preference. However, if parents expressed a preference for no treatment, some physicians were still likely to provide an antibiotic prescription if they felt such treatment was warranted. The pediatricians specializing in emergency medicine and infectious disease were aware of a recently published meta-analysis recommending prudent use of antibiotic therapy as treatment of AOM, were in agreement with its conclusions, and practiced in accordance

with its recommendations. The other physicians were not aware of the published report, and therefore would not consider modifying their clinical practice in light of its conclusions.

The following relationships emerged from the qualitative interviews:

1. *Physicians believe that parents are more likely to consult a pediatric emergency care facility when:*

a) Parents are unclear as to the cause and/or significance of their child's symptoms.

They fear that the symptoms signify potentially serious illness that poses a serious threat to their child's well being. The parents seek a medical diagnosis and medical guidance about appropriate care.

b) Parents believe their child has experienced similar illness before, and think medical intervention is required or beneficial for their child. Parents seek confirmation of their suspicions, and medical assistance and or guidance with management of their child's symptoms.

c) For both a/ and b), the parent believes that medical care is required at a particular point in time, corresponding to a time when usual or alternate health care resources are not available.

2. *Physicians are more likely to make a diagnosis of AOM when:*

a) Otoloscopic examination of the tympanic membrane reveals a bulging membrane +/- red appearance +/- decreased mobility of membrane

b) Child or parent reports symptoms of ear pain +/- irritability +/- sleep disturbance +/- fever

3. *Physicians are more likely to recommend antibiotics following AOM diagnosis when:*

- a) child < 2 years of age
- b) ear pain and/or fever is the presenting clinical symptom
- c) clinical symptoms have been present > 48 hours
- d) child has had previous episode of AOM that improved with antibiotic treatment
- e) physician diagnosis is “certain”
- f) parents express a preference for antibiotic treatment, or no treatment preference
- g) physician overestimates risk of serious complications following failure to treat case
- h) presentation time between midnight and 0800 hours

4. *Physicians are more likely to recommend a watch and wait approach following AOM diagnosis when:*

- a) child is  $\geq$  2 years of age
- b) clinical signs and symptoms have been present < 24 hours
- c) child has no history of AOM
- d) no ear-related clinical symptom is present (i.e. ear pain, ear pulling)
- e) physician not certain of diagnosis
- f) parents state a preference for expectant management
- g) concerned about inappropriate and/or overuse of antibiotics

This data provided the basis for the development of the questionnaire content.

#### 2.6.2.2. *Questionnaire Content*

The study version of the questionnaire included 43 questions. Some questions incorporated an open-ended response format, others a closed response format or Likert scale response options. The questionnaire assesses:

- how each physician currently diagnoses AOM
- self-appraisal of current antibiotic prescribing patterns
- factors believed important in antibiotic prescribing decision
- appraisal and clinical application of the scientific literature
- attitude to risk-taking and practice change

#### *Questionnaire Section 1: Diagnosis of AOM*

In an open-ended response format, physicians were asked to generate their list of clinical symptoms either reported by the parent or child or signs present on physical examination diagnostic of AOM. Physicians were asked to generate separate lists for children < 2 years and  $\geq$  2 years old. Otoscopic diagnostic criteria were solicited in a similar fashion. These open-ended questions were placed at the beginning of the questionnaire to limit potential bias from the remaining questions. Physicians were also asked to estimate the proportion of diagnosed cases in which they experienced difficulty in fully assessing the tympanic membrane, by child's age, and to indicate the instruments used to make the diagnosis.

#### *Questionnaire Section 2: Treatment Decision*

Seven hypothetical clinical scenarios depicting a child in terms of clinical and otoscopic variables were presented in the next section. Parent treatment expectations were included in several scenarios. The physician was asked to recommend one of two management options. Physicians were not asked to provide a diagnosis, or comment on their degree of diagnostic certainty (vagueness). These scenarios were designed to assess the level of clinical agreement in management decisions across the sampled physicians.

Physicians estimated the proportion of otherwise healthy children diagnosed with AOM in which they would be prepared to recommend a watch and wait strategy. They also estimated their current rate of antibiotic prescribing in all children diagnosed with AOM. Both of these questions used open-ended response formats.

### *Questionnaire Section 3: Factors Influencing Prescribing Behavior*

Physicians rated the influence of a number of factors on their prescribing behavior on a 5-point Likert rating scale (clinical leader practice, time, and parent expectations, professional practice guidelines). They also rated themselves on a 5-point Likert scale regarding their position as a clinical leader within the ED, and their willingness to change practice on the basis of scientific evidence.

### *Questionnaire Section 4: Appraisal of Current Clinical Practice*

The final section of the questionnaire asked physicians to comment on the potential effectiveness of three evidence-based strategies to stimulate self-appraisal and change in clinical practice: a parent information guide to diagnosis and management, participation in a randomized clinical trial of management options, and exposure to results of a meta-analysis.

#### *2.6.2.3. Pilot Testing to Assess Feasibility and Content Validity*

Fifteen pediatricians and family physicians not otherwise involved in the study reviewed the questionnaire to evaluate:

- Acceptability; i.e., length of questionnaire, time to complete, clarity of questions
- Content validity; i.e., accuracy and comprehensiveness of response options, feasibility of clinical vignettes

This information was used to refine the questions relating to these concepts in the study questionnaires. As well, members of the thesis committee served as an expert panel in the review of all drafts of the questionnaire. Approximately half of the physicians were aware of the recent meta-analysis on treatment of AOM, and approximately two-thirds of those aware agreed with its conclusions. Diagnostic criteria for AOM were consistent across physician specialty groups. The spelling of one drug name was corrected. The clinical scenarios were modified to reflect the typical clinical situation more closely. Their critical comments were incorporated and are reflected in the final version of the questionnaire in Appendix C.

### **2.6.3 *Physician Clinical AOM Questionnaire***

#### **2.6.3.1. *Content Development***

This questionnaire was designed to explore the effect of selected child, parent and physician factors identified in the literature review on the actual management decision in the clinical setting. Child factors explored included the age of the child and the physician perception of the severity of the clinical and otoscopic findings. Parent factors explored included the physician assessment of the parent treatment expectations and ability to adhere to the treatment recommendation. Physician factors included the rating of diagnostic certainty.

Physicians completed the 3-item questionnaire immediately following a clinical encounter with each study child diagnosed with AOM. The first question asked physicians to indicate their degree of diagnostic certainty by placing a mark on a 10 cm visual analogue scale (0 = not at all certain, 10 = absolutely certain). The second question asked physicians to identify the management decision from a list of options. The final

question used a 5-point Likert rating scale to measure the relative importance of five factors cited in the published literature and identified in pre-study physician interviews on the management decision. The questionnaire was designed to be brief, clear and easy to complete. In order to minimize physician study responsibilities, physicians were only asked to complete the form for study children given a diagnosis of AOM. As well, questionnaires were not completed for those children diagnosed with AOM whose parents declined to participate as collecting data on these encounters was not ethically justified.

#### ***2.6.4 Follow Up Parent Telephone Interview***

##### ***2.6.4.1. Content Development***

The study investigator or her delegate (for parents who indicated that they preferred the interview in French) conducted a 10-minute telephone interview with all consenting study parents 48 hours after their emergency visit. Parents were given the option of declining the interview at the time of study enrollment. The purpose of this interview was to ascertain:

- Child's clinical condition at 48 hours after the ED consultation
- Parent understanding of the diagnosis and treatment recommendation
- Parent adherence to the recommended treatment
- Consultation with other health care providers following ED consultation
- Impact of illness on the family, as determined by days of school/day care or work missed to care for child
- Parent level of satisfaction with the treatment decision
- Parent level of satisfaction with the decision making process

Two bilingual pediatric health care providers translated the telephone interview into French and then independently back-translated into English. The two English versions were judged as comparable. A bilingual pediatric nurse conducted the telephone interview with parents who expressed a preference for the French language. The nurse received training by the study investigator before conducting the interviews.

#### ***2.6.5. Emergency Medical Consultation Record***

As is standard practice at CHEO, the attending physician completed an emergency record for each child examined in the ED. The sheet, which remains part of the medical chart, records the child/parent's presenting complaint, the presenting signs and symptoms, otoscopic findings, diagnosis and treatment recommendations. The sheet also notes the presentation time, and the time seen by the examining physician (the difference reflecting a measure of waiting time in the department). This sheet was available for all children diagnosed with AOM during the study period.

#### ***2.7 Sample Size Calculation***

A sample size calculation was performed to estimate the minimum number of parent-child pairs required to determine the proportion of children diagnosed with AOM and prescribed antibiotics with a precision of 5% and a confidence of 95%. Calculations were based on the following information:

1. Approximately 2200 children presenting to the ED are diagnosed with AOM in a 12 month period
2. It is estimated that approximately 80% of all children diagnosed with AOM are treated with immediate antibiotic therapy in the ED

3. If 80% is the true frequency of antibiotic prescribing, estimation of the proportion with a precision of 5% will be acceptable (95% CI with width  $\pm 5\%$ )
4. Formula for calculation of sample size:  $n = Z^2 \cdot P(1-P) / D^2$ <sup>80</sup>

For a 95% confidence interval, a minimum sample size of 245 children was required (Appendix E). The most conservative estimate, using a proportion of children treated as 50%, was also used to calculate the sample size.

## **2.8 Ethics**

The study was reviewed and approved by the Children's Hospital of Eastern Ontario Research Ethics Committee (Appendix B). As is standard practice in the CHEO ED, registration clerks obtained parental consent following an explanation of the study. A copy of the consent form is in Appendix B. Parents were informed that their written and verbal responses would be kept confidential, and that all results would be reported in aggregate form. Parents were free to refrain from answering any question, or to withdraw from the study at any time. The process of questionnaire completion did not delay physician examination of their child. Parents were given the option to decline the telephone interview at the time of study enrollment. At the time of the telephone interview, if their child's condition was not improving or deteriorating, the parent would be advised to consult the CHEO ED telephone health line, or their family physician. The investigator would offer no medical advice. As is standard practice in the department, physicians' consent was inferred from their willingness to complete the study questionnaires. They were assured that their responses would be reported only in aggregate form. Following questionnaire completion, the investigator stored all questionnaires and emergency records in a secured cabinet in the hospital Research

Institute. Data pertaining to the parent, child and physician were entered into the computer with no personal indicators that could jeopardize confidentiality.

## **2.9 Data Analysis**

### **2.9.1 Database Development and Data Entry**

A study database was created with the assistance of the Child and Youth Clinical Trials Network (CYCTN) of the Children's Hospital of Eastern Ontario Research Institute. Data entry was provided by the CYCTN. The CHEO Research Institute Resident/Student Research Competition provided funding for this aspect of the project.

### **2.9.2.2. Descriptive Analysis**

The child and parent variables were analyzed with respect to the individual clinical encounter whereas physician variables were analyzed with respect to either the clinical encounter or a hypothetical clinical scenario, depending on the data source.

Child and parent characteristics were summarized for the entire cohort and by diagnosis (i.e. AOM or other illness). Physician characteristics were summarized. Observed differences between AOM and other illness groups were highlighted using the likelihood ratio Chi square test for categorical variables.

### **2.9.2.3. Quantification of Factors Contributing to Diagnostic and Treatment Decisions**

Two of the outcomes of interest were AOM diagnosis and prescribed antibiotics. The potential association between outcomes and child, parent and physician characteristics was investigated using logistic regression models. First, a base model adjusted for demographic variables: age (< 2 or ≥ 2 years) and gender was developed. The threshold of 2 years of age was selected because the pre-study physician interviews suggested

possible differences in physician management decisions for these age categories. Using this base model, the risk associated with a combination of physical symptoms (ear pain, ear pulling, sleep disturbance, feeding disturbance, irritability, sore throat) was quantified. Symptoms were coded as binary variables (partial method), with the absence of the symptom defined as the reference category. Collinearity of symptom variables was assessed. Tests for interactions between independent variables were performed. This procedure was designed to simulate the physician thinking process in the clinical setting. Then, the potential association between selected parent (diagnostic suspicion, treatment preference) and physician (part time or full time status) factors, and outcomes, after adjusting for demographics and clinical symptoms, was quantified in an expanded model. Parent variables were coded as categorical variables, with no opinion as the reference category. The physician variable was coded as a binary variable, with full time status defined as the reference category. Analysis of residuals was used to assess the goodness of fit of the models. For each factor, the odds ratio of an outcome and its 95% confidence interval were derived from the fitted models. These fitted models were also evaluated to determine if they could be used for outcome prediction. Two clinical scoring systems were developed to predict the two outcomes of interest in the study sample. Only clinically reproducible variables that significantly contributed to the prediction of outcome in the composite logistic regression models were selected for inclusion in the clinical score. The clinical score was derived from a rounding of the integers of the beta coefficients in the logistic regression model, following the method described by Concato<sup>89</sup> and used by Subhedar<sup>80</sup>. The probability of AOM diagnosis or antibiotic prescribing given a clinical score was calculated from the median predicted value derived

from the logistic regression model. This was compared to the observed value in the logistic regression model. A threshold clinical score value was arbitrarily selected to indicate a high and low probability of AOM diagnosis or antibiotic prescribing. Evaluated performance characteristics for prediction purposes included the sensitivity, specificity, positive and negative predictive values<sup>80</sup>.

All statistical analyses were performed using SPSS for Windows, Version 8.0

## CHAPTER 3

### Results

#### 3.1. Study Population

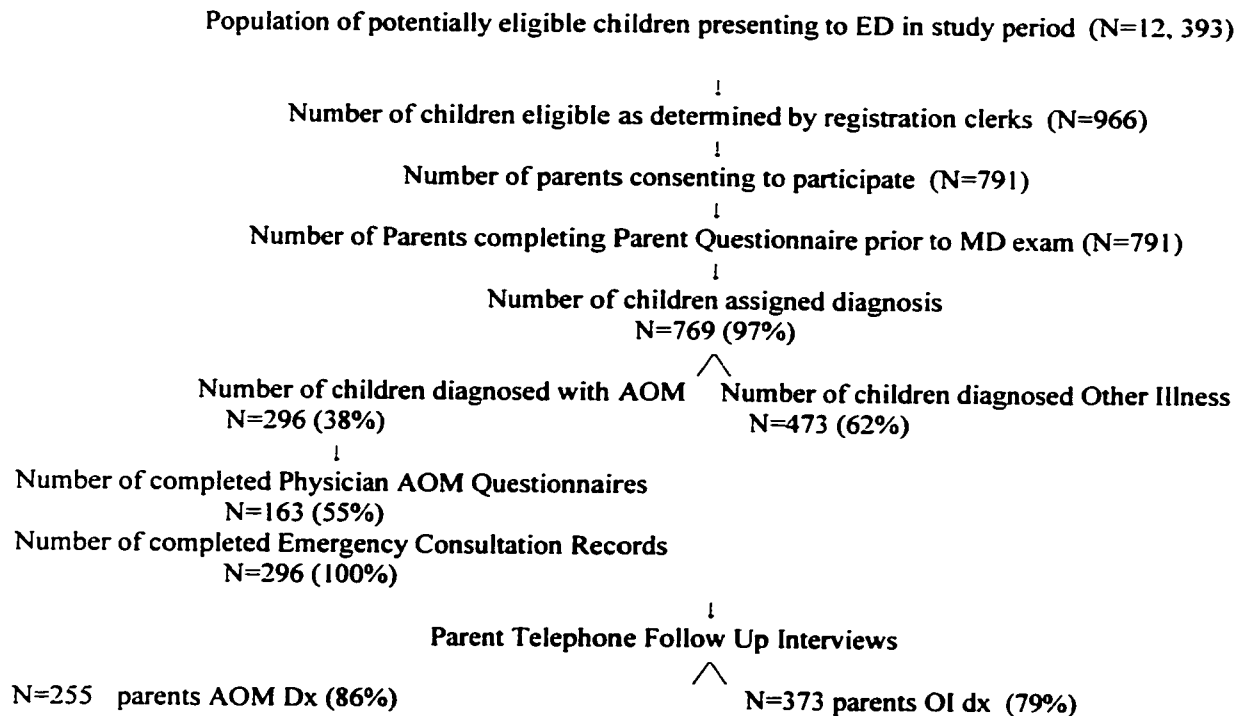
##### 3.1.1. Recruitment and Enrollment of Study Children and Parents

Twelve thousand three hundred and ninety-three children presenting to the emergency department (ED) in the study period were prospectively screened for eligibility. Nine hundred and sixty-six (8%) parent-child pairs were invited to participate in the study. One hundred seventy-five eligible parents declined, providing a study cohort of 791 parent-child pairs for a participation rate of 82 % [See Flow Diagram 3.1.2].

The reasons for parent refusal to participate in the study included:

- parent not interested in completing questionnaire (N= 169)
- parent unable to complete questionnaire as accompanied by more than one young child (N=6)

##### 3.1.2. Flow Diagram of Study Children and Parents



### ***3.1.3. Recruitment and Enrollment of Study Physicians***

Twenty-four of 35 (69%) physicians providing clinical service in the ED participated in the study. This number included all 12 of the full-time ED staff and 11 of 23 part-time physicians. This physician group completed the Baseline Physician AOM Questionnaire prior to enrollment of study children, and completed the Clinical AOM Questionnaires for study children diagnosed with AOM. Eight of 14 pediatric and emergency medicine residents indicated that they were unable to answer the questions. Six of 14 residents failed to complete the question for unknown reasons. Therefore, a decision was made to exclude residents from study participation.

### ***3.1.4. Characteristics of the Study Population***

Table 1 and 2 summarizes selected characteristics of the cohort of study children and parents, respectively, according to physician diagnosis. As no physician diagnosis was available for 22 of the 791 study children, analyses are restricted to the 769 study children with complete data. Table 3 illustrates selected characteristics of the ED study physicians. AOM patients appeared to be older than the cohort of children diagnosed with other illness (OI), were more likely not to be at home, and present to the ED with earache, ear pulling or sleep disturbance [Table 1]. Parents of children diagnosed with AOM or other illness did not differ with respect to language or educational level [Table 2]. Most ED physicians were female pediatricians with less than 10 years of ED experience [Table 3].

**Table 1: Selected Characteristics of Study Children**

| <b>Characteristic</b>             | <b>All Study Children<br/>N=769<br/>n (%)</b> | <b>Children diagnosed with<br/>AOM N=296<br/>n (%)</b> | <b>Children diagnosed with<br/>Other Illness N=473<br/>n (%)</b> | <b>P value*</b> |
|-----------------------------------|---|--|--|-----------------|
| <b>Child's Age</b>                |   |  |  |                 |
| Toddlers (<2 years)               | 330 (43)                                      | 105 (38)   | 225 (47)   | 0.005           |
| <b>Child's Gender</b>             |   |  |  |                 |
| Male                              | 405 (52)                                      | 155 (52)   | 250 (51)   | 0.712           |
| <b>Symptoms</b>                   |   |  |  |                 |
| Earache                           | 294 (38)                                      | 205 (70)   | 89 (18)  | <0.001          |
| Ear Pulling                       | 224 (29)                                      | 143 (49)   | 81 (16)  | <0.001          |
| Sleep Disturbance                 | 421 (55)                                      | 186 (64)   | 238 (48)   | <0.001          |
| Fever                             | 523(68)                                       | 161 (55)   | 362 (74)   | <0.001          |
| Irritability                      | 376 (49)                                      | 147 (50)   | 229 (47)   | 0.37            |
| Decreased Feeding                 | 411 (53)                                      | 127 (43)   | 284 (59)   | <0.001          |
| Sore Throat                       | 192 (25)                                      | 70 (24)  | 122 (25)   | 0.03            |
| <b>Exposure to Tobacco</b>        | 201 (26)                                      | 75 (26)  | 131 (27)   | 0.135           |
| <b>Exposure to Other Children</b> |   |  |  |                 |
| Home                              | 271 (35)                                      | 89 (31)  | 182 (40)   | 0.005           |
| Day Care                          | 266 (34)                                      | 105 (37)   | 161 (34)   |                 |
| School                            | 217 (28)                                      | 91 (32)  | 126 (26)   |                 |

\* p value displayed for descriptive purposes only – not for confirmation of group differences.

**Table 2. Selected Characteristics of Study Parents**

| <i>Characteristic</i>        | <i>All Study Parents</i> | <i>Parents of AOM Children</i> | <i>Parents of OI Children</i> | <i>P</i>      |
|------------------------------|--------------------------|--------------------------------|-------------------------------|---------------|
|                              | <i>N=769</i>             | <i>N=296</i>                   | <i>N=473</i>                  | <i>value*</i> |
|                              | <i>n (%)</i>             | <i>n (%)</i>                   | <i>n (%)</i>                  |               |
| <b>Language</b>              |                          |                                |                               | 0.672         |
| English                      | 655 (85)                 | 250 (84)                       | 405 (86)                      |               |
| <b>Education<sup>1</sup></b> |                          |                                |                               | 0.225         |
| Some High School             | 110 (14)                 | 46 (16)                        | 64 (13)                       |               |
| Completed High School        | 179 (23)                 | 66 (22)                        | 113 (24)                      |               |
| College Diploma              | 231 (30)                 | 80 (27)                        | 151 (32)                      |               |
| University Degree            | 249 (32)                 | 104 (35)                       | 145 (31)                      |               |

\* *p* value displayed for descriptive purposes only – not for confirmation of group differences.

<sup>1</sup> Highest level of education attained by either parent

**Table 3. Characteristics of Study Physicians**

| <i>Characteristic</i>                                  | <i>N=24</i>  |
|--|--------------|
|  | <i>N (%)</i> |
| <b>Specialty</b>                                       |              |
| Pediatrician   | 22 (92)      |
| • Emergency Medicine                                   | 14 (58)      |
| • Other Specialty                                      | 8 (33)       |
| Family Physician                                       | 2 (8)        |
| <b>Gender</b>  |              |
| Male   | 9 (37)       |
| <b>Years in Practice in ED</b>                         |              |
| ≤ 10 years   | 19 (79)      |
| Median [25 <sup>th</sup> , 75 <sup>th</sup> quartiles] | 10 [6-17]    |
| <b>Hours/Week Worked in ED</b>                         |              |
| Median [25 <sup>th</sup> , 75 <sup>th</sup> quartiles] | 27 [8-40]    |
| <b>Community Practice</b>                              | 6 (25)       |

### **3.2 Objective 1:**

***To describe factors contributing to the Parent Decision to Seek Medical Consultation in the Emergency Department***

#### ***3.2.1. Children's Symptoms at Time of Medical Consultation***

Table 4 displays the frequency with which selected symptoms were reported by parents at the time of ED presentation. Parents of children diagnosed with AOM were most likely to report that their child exhibited earache or ear pulling or sleep disturbance, whereas parents of children diagnosed with other illness were more likely to report fever or decreased feeding. Fever was the most frequently noted symptom in the study cohort. Irritability and sore throat did not differentiate between the two diagnostic groups.

Time of presentation in the ED was bimodal; most study children presented at 2000 hours and 2330 hours (median 1651 hours) [Table 4]. Parents of children diagnosed with AOM tended to consult the ED sooner in the illness than parents of children diagnosed with other illness [Table 4].

Parents of children diagnosed with AOM were more likely to have administered at least one dose of pain-relief medicine (i.e. Advil) prior to ED consultation, whereas parents of children diagnosed with other illness were more likely to have administered at least one dose of medicine to reduce fever (i.e. Tylenol). These differences in treatment strategies, in part, reflect the differences in symptom presentation between the two groups.

**Table 4: Selected factors related to the Parent Decision to Seek Medical Consultation in the ED**

| Variable                                      | All Study Children<br>N=769 | Children Diagnosed with AOM<br>N=296 | Children Diagnosed with Other<br>Illness N=473 | P value* |
|---|-----------------------------|--------------------------------------|--|----------|
| <b>Parent Diagnosis</b>                       |                             |                                      |  |          |
| Suspected AOM                                 | 274 (36)                    | 195 (66)                             | 79 (17)  | <0.001   |
| Suspected Other Illness                       | 495 (64)                    | 101 (34)                             | 394 (83)                                       |          |
| <b>Child Symptoms<sup>1</sup></b>             |                             |                                      |  |          |
| Earache                                       | 294 (38)                    | 205 (70)                             | 89 (18)  | <0.001   |
| Ear Pulling                                   | 224 (29)                    | 143 (49)                             | 81 (16)  | <0.001   |
| Sleep Disturbance                             | 421 (55)                    | 186 (64)                             | 238 (48)                                       | <0.001   |
| Fever   | 523 (68)                    | 161 (55)                             | 362 (74)                                       | <0.001   |
| Irritability                                  | 376 (49)                    | 147 (50)                             | 229 (47)                                       | 0.374    |
| Decreased Feeding                             | 411 (53)                    | 127 (43)                             | 284 (59)                                       | <0.001   |
| Sore Throat                                   | 192 (25)                    | 70 (24)                              | 122 (25)                                       | 0.727    |
| <b>Duration of Child Symptoms</b>             |                             |                                      |  |          |
| ≤ 48 hours                                    | 542 (70)                    | 218 (74)                             | 324 (68)                                       | 0.032    |
| <b>Parent Treatment Strategies</b>            |                             |                                      |  |          |
| Medicine to reduce fever                      | 432 (56)                    | 134 (45)                             | 298 (63)                                       | <0.001   |
| Medicine to reduce pain                       | 268 (35)                    | 144 (49)                             | 124 (26)                                       | <0.001   |
| <b>Time of Presentation to ED<sup>2</sup></b> |                             |                                      |  |          |
| 0800-1559 hours                               | 161 (21)                    | 51 (17)                              | 110 (24)                                       |          |
| 1600-2159 hours                               | 338 (44)                    | 112 (35)                             | 226 (50)                                       |          |
| 2200-0759 hours                               | 249 (32)                    | 133 (45)                             | 116 (26)                                       |          |
| <b>Reason for ED Presentation</b>             |                             |                                      |  |          |
| Need diagnosis                                | 289 (37)                    | 101 (34)                             | 188 (40)                                       |          |
| Symptom severity                              | 579 (75)                    | 222 (75)                             | 357 (73)                                       |          |
| Symptom duration                              | 427 (56)                    | 133 (47)                             | 294 (60)                                       |          |
| Fear needs hospitalization                    | 90 (11)                     | 21 (7)                               | 69 (14)  |          |
| Script needed for work                        | 60 (8)                      | 37 (13)                              | 23 (5)   |          |
| MD office closed                              | 335 (44)                    | 150 (51)                             | 185 (39)                                       |          |
| Referred by other MD                          | 55 (7)                      | 11 (4)                               | 41 (9)   |          |
| No family doctor                              | 39 (5)                      | 10 (4)                               | 29 (6)   |          |
| Convenience                                   | 103 (13)                    | 40 (14)                              | 63 (13)  |          |

<sup>1</sup>Some children presented with more than one symptom, therefore the total frequency exceeds 100%.:<sup>2</sup> 21 missing

### 3.2.2. Parent Diagnosis

Parents reported what they suspected was the nature of their child’s problem. The level of agreement beyond chance (Kappa) between parent and physician diagnosis was 0.57 ( $\pm .06$ ).

Overall, 274/769 (36%) parents who answered the question explicitly stated that they thought their child had an ear infection [Table 4] and 195 (71%) of these parents were correct. The children of the seventy-nine (29%) parents who incorrectly suspected an ear infection were diagnosed with either viral illness or upper respiratory tract infection. Parents of 495 children (64%) did not suspect an ear infection. Instead, they suspected that their child was suffering from a cold, viral illness, gastrointestinal upset or breathing problem. One hundred and one children (20%) of this group were diagnosed with an ear infection. Hence, the sensitivity, specificity, positive predictive value and negative predictive value of the parent diagnosis were 66% ( $\pm 3\%$ ), 83% ( $\pm 2.7\%$ ), 71% ( $\pm 3\%$ ) and 79% ( $\pm 2.9\%$ ), respectively [Table 5].

**Table 5: Concordance between Parent and Physician Diagnosis**

|                         | MD Diagnosis |               | Total      |
|-------------------------|--------------|---------------|------------|
|                         | AOM          | Other Illness |            |
| <b>Parent Diagnosis</b> |              |               |            |
| AOM (Ear Infection)     | 195          | 79            | <b>274</b> |
| Other Illness           | 101          | 394           | <b>495</b> |
| <b>Total</b>            | <b>296</b>   | <b>473</b>    | <b>769</b> |

### 3.2.3. Parents’ Reasons for Medical Consultation in the Emergency Department

Parents consulted the ED when they required interpretation of and guidance regarding the management of their child’s symptoms and when their usual health care resources were unavailable.

The frequencies of frequently reported reasons for medical consultation are displayed in Table 4.

Thirty-six percent of parents suspected that their child had an ear infection, wished confirmation of their suspicions, and medical assistance with management of the symptoms. Sixty-seven percent of these parents based their judgment on the similarity of the child's current symptoms to those present during previous AOM episodes. One third of these children had a history of multiple ear infections, and had been previously referred to the hospital-based ENT service. These parents selectively bypassed their family physician in favor of the ED, because they believed further consultation with the ENT department might be required.

Thirty-seven percent of parents were uncertain as to the cause of their child's symptoms, wished a medical diagnosis and help to manage their child's symptoms. A greater proportion of parents of children diagnosed with other illness than parents of children diagnosed with AOM feared that hospitalization might be required (i.e. children with fever or feeding disturbance).

### **3.3. Objective 2: To describe factors contributing to the Physician Diagnostic Decision in Children with Suspected AOM**

#### **3.3.1. Physician Diagnostic Decision**

Of the 769 children enrolled in the study, 296 (38%) were diagnosed with AOM and 473 (62%) were diagnosed with other illness (OI). Other illnesses diagnosed included viral illness, gastroenteritis, cold/flu (upper respiratory illness), and asthma. Children presented with similar physical symptoms as noted in Table 4. A diagnosis of AOM was based on the clinical judgment of the attending physician. Thirty physicians made diagnoses in the study children. Each diagnosis reflected a physician's interpretation of the clinical signs and symptoms reported by the parent and/or present on clinical examination and findings on standard otoscopic examination. No objective diagnostic procedures, such as tympanometry, acoustic reflectometry or tympanocentesis and middle ear fluid culture, were performed, in accordance with usual clinical practice.

#### **3.3.2. Potential Child Factors contributing to the Physician Diagnostic Decision**

The following section quantifies the contribution of selected child factors to the physician diagnostic decision. Odds ratios (OR) and 95% confidence intervals [95% CI] are reported.

- **Age**

Children at least two years old were 50% more likely to be diagnosed with AOM than children less than two years old (OR 1.53 [1.14-2.16]).

- **Clinical Symptoms**

After controlling for the effects of age and gender, physical symptoms that were independently associated with the physician diagnosis of AOM were the presence of earache, ear pulling, and sleep disturbance, and the absence of fever and feeding disturbance [Table 6]. Children presenting with earache were 8 times

**Table 6: Potential Child Factors contributing to the Physician Diagnosis of AOM (N=769)**

| <b>Factor</b>                          | <b>Reference Level</b>     | <b>Odds Ratio</b> | <b>95% CI</b> | <b>P value*</b> |
|--|----------------------------|-------------------|---------------|-----------------|
| <b>Age &gt; 2 years</b>                | ≤2 years                   | 1.53              | 1.14- 2.06    | 0.005           |
| <b>Gender</b>                          | Male                       | 1.07              | 0.8- 1.42     | 0.703           |
| <b>Presenting Symptoms<sup>1</sup></b> |                            |                   |               |                 |
| Earache                                | No earache                 | 7.9               | 5.2-12.1      | <0.00013        |
| Ear Pulling                            | No ear pulling             | 1.8               | 1.2- 2.8      | 0.0055          |
| Sleep Disturbance                      | Normal sleep               | 1.5               | 1.004- 2.1    | 0.048           |
| Fever                                  | No fever                   | 0.79              | 0.45- 0.99    | 0.047           |
| Irritability                           | No irritability            | 1.27              | 0.94- 1.71    | 0.682           |
| Decreased Feeding                      | Normal feeding             | 0.60              | 0.51- 1.11    | 0.156           |
| Sore Throat                            | No sore throat             | .87               | 0.62- 1.23    | 0.44            |
| <b>Symptom Duration<sup>2</sup></b>    |                            |                   |               |                 |
| ≥48 hours                              | <48 hours                  | 0.71              | 0.48- 1.05    | 0.084           |
| <b>History Of AOM<sup>3</sup></b>      |                            |                   |               |                 |
|  | First episode <sup>3</sup> | 1.36              | 0.94- 1.97    | 0.096           |
| <b>Day care exposure<sup>4</sup></b>   |                            |                   |               |                 |
|  | Home                       | 1.4               | 0.91- 2.2     | 0.24            |
| <b>Tobacco Exposure<sup>5</sup></b>    |                            |                   |               |                 |
|  | No exposure                | 0.75              | 0.5- 1.1      | 0.17            |

\* Alpha value of 0.05 used as marker of statistical significance. Odds ratios and 95% confidence intervals obtained with multivariate logistic regression analysis (enter method)

<sup>1</sup> Age and gender were base factors included in all analyses. Reference categories were age < 2 years and male gender. Symptoms were considered as a composite, adjusting for the effects of other symptoms. Reference category is absence of the symptom.

<sup>2</sup> Adjusted for age, gender and symptom presentation. Reference category < 48 hours duration

<sup>3</sup> Adjusted for age, gender, symptoms and symptom duration. Reference category: no history of AOM.

<sup>4</sup> Reference category: home, adjusted for age, gender, symptom presentation and symptom duration

<sup>5</sup> Reference category: no exposure to tobacco, adjusted for age, gender, symptom presentation and symptom duration

more likely to be diagnosed with AOM than children presenting with no ear pain (OR 7.9; [5.2-12.1]). Children with ear pulling were twice as likely to be diagnosed with AOM than children without ear pulling (OR 1.84 [1.2- 2.8]) as were children presenting with sleep disturbance (OR 1.5[1.004- 2.1]). Children presenting with fever, after accounting for other symptoms, were twenty percent less likely to receive a diagnosis of AOM than children presenting without fever (OR 0.79[0.45- 0.99]).

- ***Duration of Symptoms***

Children with symptoms of more than 48 hours duration were 30% less likely to be diagnosed with AOM than children presenting with symptoms of less than 48 hours duration, after controlling for the effects of child's age, gender, and symptom presentation (OR 0.71[0.48-1.05]). This was not statistically significant.

- ***History of AOM***

Those study children with a history of AOM were 40% more likely to receive a medical diagnosis of AOM than were those children with no history of AOM (OR 1.36[0.94-1.97]), after adjusting for all other factors in the multivariate analysis. As well, children attending day care or school, after controlling for the effects of age, symptom presentation and symptom duration, were 40% more likely to receive a medical diagnosis of AOM than children at home (OR 1.4[0.91-2.2]). These variables did not attain statistical significance.

### ***3.3.3. Potential Parent Factors contributing to the Physician Diagnostic Decision***

- ***Parent Diagnostic Suspicion***

The children of parents who suspected an ear infection were three and a half times more likely to be diagnosed with AOM than children whose parents expressed no diagnostic opinion, after controlling for the effects of child's age, gender, symptoms, symptom duration and previous history

of AOM (OR 3.6 [1.9-6.7]). In contrast, children whose parents suspected another illness were only half as likely to receive a diagnosis of AOM in comparison to parents with no diagnostic suspicion [Table 7].

**Table 7: Potential Parent Factors contributing to the Physician Diagnosis of AOM (N=660\*)**

| <b>Parent Factor</b>                         | <b>Reference</b>    | <b>Odds Ratio<sup>1</sup></b> | <b>95% CI</b> | <b>P value</b> |
|--|---------------------|-------------------------------|---------------|----------------|
| <i>Parent Diagnosis</i>                      | No opinion          |                               |               | <0.001         |
| 1. Suspected Ear Infection                   |                     | 3.59                          | 1.93- 6.7     |                |
| 2. Suspected Other Illness                   |                     | 0.52                          | 0.28-0.98     |                |
| <i>Parent Belief in Value of Antibiotics</i> | No opinion          |                               |               | 0.0005         |
| 1. Positive                                  |                     | 2.47                          | 1.56-3.89     |                |
| 2. Negative                                  |                     | 1.39                          | 0.56-3.46     |                |
| <i>Education Level</i>                       |                     |                               |               | 0.5            |
| High school or less                          | University graduate | 0.7                           | 0.4- 1.2      |                |

<sup>1</sup> Odds ratios computed using multivariate logistic regression analysis, controlling for the effects of child's age, gender, symptom composite and symptom duration, and parent factors (parent belief in value of antibiotics or parent diagnosis)

\* 131 missing cases excluded from analysis

• **Parent Belief about the Value of Antibiotic Therapy**

In comparison to the children of parents who voiced no opinion about the value of antibiotic therapy, children of parents who believed antibiotics would be of benefit were two and a half times as likely to receive a medical diagnosis of AOM (OR 2.47 [1.6-3.9]). Children of parents who suspected antibiotics would be of little benefit were forty percent as likely to receive a medical diagnosis of AOM than children for whom parents had no opinion, though the confidence intervals included 1 (OR 1.39 [0.56-3.46] [Table 7]).

### 3.3.4. Potential Physician Factors contributing to a Physician Diagnostic Decision

- **Physician Status (Full time or Part time)**

Full-time physicians examined and made diagnoses in 461/769 (60%) study children. However, study physicians providing clinical service on a part-time basis were twice as likely to diagnose AOM in a study child than full-time ED physicians [Table 8], after controlling for the effects of the child and parent factors itemized in *section 3.3.4* (OR 2.01[1.3-3.1]).

**Table 8. Physician Factors contributing to a Diagnosis of AOM, adjusted for Child and Parent Factors (N=573\*)**

| <i>Physician Factor</i>          | <i>Reference</i> | <i>Odds Ratio<sup>†</sup></i> | <i>95% CI</i> | <i>P value</i> |
|----------------------------------|------------------|-------------------------------|---------------|----------------|
| <i>Part time Work Status</i>     | Full Time        | 2.01                          | 1.3-3.1       | 0.001          |
| <i>&gt; 10 Years in Practice</i> | ≤ 10 years       | 0.87                          | 0.56-1.36     | 0.54           |

<sup>†</sup> Odds ratios computed using multivariate logistic regression analysis, controlling for effects of child's age, gender, symptom composite, duration of symptoms, parent diagnosis and parent belief that antibiotics will benefit child

\*196 missing cases

Goodness of fit Chi square of model 6.59 df 8 P=0.58

#### 3.3.4.2. Physician Characteristics, by Work Status

Selected characteristics of the ED physician group were examined to understand the difference in diagnosis between part time and full time physician work status. These factors included diagnostic criteria, difficulty in physical examination of the young child, and diagnostic certainty ratings. The data for the first two factors were obtained from the Baseline Physician Questionnaire (N=24). The diagnostic certainty rating data was obtained from the Clinical AOM Questionnaires (N=163).

- **AOM Diagnostic Criteria**

In the Baseline Physician Questionnaire, study physicians listed the physical examination findings that they used to make a diagnosis of AOM. Table 9 ranks the five most frequently listed diagnostic

criteria for physical examination and otoscopy. There were no differences in the diagnostic criteria generated by the 24 full-time and part-time ED physicians who completed the questionnaire and made study AOM diagnoses. The written diagnostic criteria did not differ by physician specialty (emergency medicine, pediatrics or family medicine).

Fever figures prominently in the list of physical exam criteria for children of all ages, but did not predict AOM diagnosis in clinical practice [Table 4]. Twenty-one physicians listed fever for the child under 2 years, and twelve physicians listed fever for the child over 2 years. Ear pain emerges as a consistent criterion for the study physicians when examining a child over the age of two years. Ear pain also appeared to be the most significant predictor of AOM diagnosis in clinical practice [Table 4]. Otoscopic criteria did not differ by age category. Physicians reported variations in the color, mobility, and position of the middle ear anatomy.

**Table 9: Ranking of Physician Diagnostic Criteria for AOM**

| <i>Ranking</i> | <i>Physical Exam Criteria<br/>For Child &lt; 2 years</i>    | <i>Physical Exam Criteria<br/>For Child &gt; 2 years</i>         | <i>Otosopic Criteria for Child All<br/>Ages</i>                          |
|----------------|---|--|--|
| 1              | Acute pain or fever or irritability<br>or ear pulling (N=7) | Ear Pain (N=8)   | Diffuse erythema and bulging<br>bullous TM (N=3)                         |
| 2              | No signs (N=3)  | Ear pain and fever (N=5)   | Red TM with fluid behind TM<br>(N=3)                                     |
| 3              | Fever or irritability or URI (N=3)                          | Ear pain and fever and URI (N=3)                                 | Red TM with fluid and distorted<br>anatomy (N=3)                         |
| 4              | Fever or irritability and feeding<br>disturbance (N=2)      | Ear pain and high fever<br>And hearing difficulties (N=2)        | Bulging, red TM, with fluid behind<br>and loss of light reflex (N=2)     |
| 5              | Fever and URI and irritability and ear<br>pulling (N=2)     | Ear pain, loss of hearing and<br>Bloody discharge from ear (N=2) | Bulging or retracted or red TM, or<br>red with absent light reflex (N=2) |

*TM tympanic membrane, URI upper respiratory infection*

- ***Estimation of Difficulty Associated with Physical Examination of the Young Child***

Twenty-two of 24 (92%) physicians reported that they had almost no difficulty in fully visualizing the TM in diagnosed AOM cases. Two physicians noted that they do not make a diagnosis of AOM without visualization of the tympanic membrane, therefore they were able to fully visualize the TM in all cases. This did not differ by physician work status.

- ***Physician Diagnostic Certainty***

Diagnostic certainty ratings (number between 0-10, with 10 being “absolutely certain”) recorded by physicians on the Clinical AOM Questionnaire (see *Section 2.6.3.*) are available for 163 of the 296 (55%) AOM diagnoses. Overall, study physicians reported high levels of diagnostic certainty. The distribution of ratings was positively skewed toward a score of 10. For example, when ear pain was present, 58 of the 110 ratings (53%) were 10. When fever was absent, 36 of 71(51%) certainty ratings were 10. Table 10 shows median certainty scores for the study cohort, by age and symptom categories. The median certainty scores did not differ by physician work status. The presence of a symptom in children over 2 years appeared to generate more precise certainty estimates. Earache was the only symptom that discriminated between higher and lower median certainty scores.

**Table 10. Diagnostic Certainty Ratings in AOM Diagnoses, by Selected Factors (N=163)**

| <b>Factor</b>     |           | <b>N=163</b> | <b>Median</b> | <b>Inter-quartile Range</b> |
|-------------------|-----------|--------------|---------------|-----------------------------|
| Age               | ≤ 2 years | 55           | 8.5           | [5-10]                      |
|                   | >2 years  | 108          | 10            | [8.5-10]                    |
| Earache           | Present   | 110          | 10            | [8.2-10]                    |
|                   | Absent    | 53           | 8.7           | [5-10]                      |
| Fever             | Present   | 87           | 9.4           | [7.1-10]                    |
|                   | Absent    | 76           | 10            | [7.6-10]                    |
| Ear Pulling       | Present   | 80           | 9.5           | [8.2-10]                    |
|                   | Absent    | 83           | 9.8           | [6.2-10]                    |
| Irritability      | Present   | 85           | 9.4           | [7.5-10]                    |
|                   | Absent    | 78           | 10            | [7-10]                      |
| Sleep Disturbance | Present   | 105          | 9.6           | [7.5-10]                    |
|                   | Absent    | 58           | 9.7           | [6.4-10]                    |
| Decreased Feeding | Present   | 74           | 9.6           | [7.4-10]                    |
|                   | Absent    | 89           | 9.7           | [7.1-10]                    |
| Sore Throat       | Present   | 36           | 10            | [6.3-10]                    |
|                   | Absent    | 127          | 9.6           | [7.4-10]                    |
| Physician Status  | Full time | 102          | 9.8           | [7.2-10]                    |
|                   | Part time | 61           | 9.8           | [6.8-10]                    |

**3.4 Objective 4: To evaluate the performance of the composite factors in the prediction of a physician diagnosis of AOM**

The composite model predicting the physician clinical diagnosis of AOM is a logistic combination of the following variables, in addition to random error:

- *Child's Age*
- *Child's Gender*
- *Presence of Earache*
- *Absence of Fever*
- *Parent Suspicion of AOM*
- *Parent Belief in Value of Antibiotics Today*
- *Physician Work Status (Full time versus Part time)*

The performance characteristics of the composite model are displayed in Table 11. The overall accuracy was 80%. The model sensitivity was 72% ( $\pm 3.6\%$ ), specificity was 85% ( $\pm 2.9\%$ ), positive predictive value ( $76\% \pm 3.4$ ), negative predictive value ( $83\% \pm 3\%$ ).

**Table 11: Performance Characteristics of Composite Model Predicting Physician Diagnosis (N=594\*)**

| <i>Observed</i>              |            |                      |              |
|------------------------------|------------|----------------------|--------------|
| <i>Predicted<sup>1</sup></i> | <i>AOM</i> | <i>Other Illness</i> | <i>Total</i> |
| <i>AOM</i>                   | 164        | 54                   | 218          |
| <i>Other Illness</i>         | 64         | 312                  | 376          |
| <i>Total</i>                 | 228        | 366                  | 594          |

<sup>1</sup>Cutoff value of 0.50

\* 175 cases missing: 68 of AOM diagnoses and 107 of OI diagnoses

A clinical scoring system was developed to predict a clinical diagnosis of AOM. Only variables that could be empirically confirmed by an examining physician using standard, readily available

examination tools, and that significantly contributed to the prediction of AOM diagnosis in the composite model were selected for inclusion in the clinical score. These were the clinical variables of age ( $\leq$  or  $>$  2 years), gender (male or female), presence of earache and presence of fever. Parent and physician variables were not included, as they were not considered reliable markers of prediction. The clinical score was derived from a rounding of the integers of the beta coefficients in the logistic regression model. The probability of AOM diagnosis given a clinical score was calculated from the median predicted value derived from the logistic regression model. This was compared to the observed value in the logistic regression model. A threshold clinical score value was arbitrarily selected to indicate a high and low probability of AOM diagnosis.

**Table 12: Clinical Scoring System for AOM Diagnostic Decision**

| <i>Variable</i>        | <i>Reference Category</i> | <i>Beta Coefficient<sup>1</sup></i> | <i>Integer Score<sup>2</sup></i> |
|------------------------|---------------------------|-------------------------------------|----------------------------------|
| Age $\leq$ 2 years old | $>$ 2 years               | 0.38                                | 2                                |
| Male gender            | Female                    | 0.18                                | 1                                |
| No Fever               | Presence of fever         | 0.41                                | 2                                |
| Presence of earache    | No earache                | 2.4                                 | 12                               |

<sup>1</sup> Derived from multivariate logistic regression analysis model including variables of child's age, gender, earache, absence of fever.  
<sup>2</sup> Derived by multiplying beta coefficient by factor of 5.

To test the scoring system, the predicted and observed probability of AOM with various combinations of variables yielding different clinical scores, were calculated. These are displayed in Table 13.

**Table 13: Observed and Predicted Probability of AOM Diagnosis**

| Variable Combination        | Clinical Score | N   | Observed Value | Predicted Value |
|-----------------------------|----------------|-----|----------------|-----------------|
| No earache, fever, F. >2    | 0              | 76  | .08            | .12             |
| No earache, fever, F. <2    | 2              | 102 | .23            | .17             |
| No earache, fever, M. >2    | 1              | 104 | .10            | .14             |
| No earache, fever, M. <2    | 3              | 89  | .28            | .20             |
| No earache, no fever, F. >2 | 2              | 23  | .09            | .17             |
| No earache, no fever, F. <2 | 4              | 21  | .17            | .23             |
| No earache, no fever, M. >2 | 3              | 21  | .10            | .20             |
| No earache, no fever, M. <2 | 5              | 42  | .26            | .27             |
| Earache, fever, F.<2        | 12             | 57  | .63            | .61             |
| Earache, fever, M.>2        | 14             | 22  | .64            | .70             |
| Earache, fever, M.<2        | 13             | 46  | .67            | .65             |
| Earache, No fever, F. >2    | 15             | 28  | .50            | .73             |
| Earache, No fever, F.<2     | 14             | 55  | .76            | .70             |
| Earache, No fever, M.>2     | 16             | 9   | .56            | .78             |
| Earache, No fever, M.<2     | 15             | 65  | .85            | .74             |
|                             | 17             | 9   | .56            | .81             |

There is a positive correlation between the observed and predicted values (Spearman's rho 0.799,  $p < 0.01$ ). A clinical score of 12 is arbitrarily selected as a threshold point: with values  $< 12$  (i.e. no earache) suggestive of low probability of a diagnosis of AOM, and clinical scores of  $\geq 12$  (presence of earache) suggestive of a higher likelihood of AOM diagnosis. This is clinically sensible, as the presence of earache contributed most significantly to the prediction of AOM diagnosis in the study sample.

**Table 14: Classification Table using Clinical Scoring System, with cutoff value of 12 (N=769)**

| Predicted                  | Observed |               |       |
|----------------------------|----------|---------------|-------|
|                            | AOM      | Other Illness | Total |
| Score $\geq 12$ AOM        | 202      | 89            | 291   |
| Score $< 12$ Other Illness | 84       | 394           | 478   |
| Total                      | 286      | 483           | 769   |

The performance characteristics of the clinical scoring system are displayed in Table 14. The model sensitivity was 71% ( $\pm 3\%$ ), specificity was 82% ( $\pm 2.7\%$ ), positive predictive value 69% ( $\pm 3.2\%$ ) and negative predictive value 82% ( $\pm 2.7\%$ ). Given that this model has fewer variables than the best fitting model described above, the clinical scoring model serves reasonably well (with cutoff value of 12) in predicting the physician diagnosis of AOM in this sample.

**3.5 Objective 5: To describe factors contributing to the Physician Antibiotic Prescribing Decision in Children Diagnosed with AOM**

**3.5.1 Physician Antibiotic Prescribing Decision**

Seventy-eight percent of the study children diagnosed with AOM were treated with immediate antibiotic therapy [Table 15].

**Table 15: Physician Treatment Decision in Children diagnosed with AOM**

| <i>Physician Treatment Decision</i>                  | <i>AOM Diagnoses</i>     |
|--|--------------------------|
|  | <i>N=282<sup>1</sup></i> |
|  | <i>N (%)</i>             |
| 1. Immediate antibiotics & analgesia                 | 221 (78)                 |
| 2. Watch and wait, with prescription for antibiotics | 31 (12)                  |
| 3. Watch and wait, no prescribed follow-up           | 27 (10)                  |

<sup>1</sup>Evaluable children only, 14 cases missing

**3.5.2. Potential Child Factors contributing to the Physician Antibiotic Prescribing Decision**

- **Child's Age**

Children less than 2 years of age were no more likely to receive antibiotic therapy following a diagnosis of AOM than children at least 2 years of age (OR 0.57[.29-1.12]) [Table 16]. The 24 study physicians indicated that the age of the child did not significantly influence their prescribing decision in 129 of the 163 (79%) clinical AOM diagnoses with completed physician data.

- **Type and Duration of Symptoms**

The presence of earache and fever appeared to significantly contribute to the physician decision to prescribe immediate antibiotic therapy [Table 16]. Children of similar age and gender diagnosed with AOM and presenting with earache were three times more likely to receive antibiotics than children without ear pain (OR 3.45[1.4-8.6]). Similarly, children presenting with fever were 3 times as likely as those without fever to receive immediate antibiotic therapy (OR 3.0 [1.5-6.1]).

After controlling for the effects of age, gender and presenting symptom, symptom duration and a history of AOM did not significantly influence the prescribing decision.

**Table 16: Child factors and the Physician Antibiotic Prescribing Decision (N=242\*)**

| <i>Factor</i>                       | <i>Reference</i> | <i>Odds Ratio<sup>1</sup></i> | <i>95% CI</i> | <i>P value</i> |
|-------------------------------------|------------------|-------------------------------|---------------|----------------|
| <i>Age<sup>2</sup></i>              | < 2 years        | 0.57                          | 0.29- 1.12    | 0.10           |
| <i>Gender<sup>3</sup></i>           | Male             | 1.11                          | 0.61- 2.04    | 0.74           |
| <i>Symptoms<sup>4</sup></i>         |                  |                               |               |                |
| Earache                             | No ear pain      | 3.45                          | 1.4- 8.6      | 0.008          |
| Ear Pulling                         | No ear pulling   | 0.54                          | 0.27- 1.1     | 0.09           |
| Sleep Disturbance                   | Normal sleep     | 1.34                          | 0.65- 2.7     | 0.43           |
| Fever                               | No fever         | 3.0                           | 1.5- 6.1      | 0.002          |
| <i>Symptom Duration<sup>5</sup></i> |                  |                               |               |                |
| <i>≥48 hours</i>                    | <48 hours        | 1.2                           | 0.54- 2.66    | 0.66           |
| <i>Previous AOM<sup>6</sup></i>     |                  |                               |               |                |
| AOM before                          | First episode    | 0.7                           | 0.32-1.5      | 0.33           |

*54 missing cases*

<sup>1</sup> Odds ratios computed using multiple logistic regression analysis

<sup>2,3,4</sup> Age and gender were base factors included in all analyses. Reference categories were age < 2 years and male gender. Symptoms were considered as a composite, adjusting for the effects of other symptoms. Reference category is absence of the symptom. Odds ratios and 95% confidence intervals obtained with multivariate logistic regression analysis<sup>5</sup>

<sup>5</sup> Adjusted for age, gender and symptom presentation. Reference category < 48 hours duration

<sup>6</sup> Adjusted for age, gender, symptoms and symptom duration. Reference category: no history of AOM.

Goodness of fit chi square 10.36, df8, p=0.24, Model accuracy 80%, 100% of antibiotic prescriptions predicted correctly, 9% of WW recommendations predicted correctly

### **3.5.3. Potential Parent Factors contributing to the Physician Antibiotic Prescribing Decision**

Parent diagnosis and treatment preference had little influence on the physician prescribing decision [Table 17]. Children of parents who suspected that their child had an ear infection were almost three times as likely to receive antibiotics as those whose parents had no diagnostic opinion (OR 2.66[0.69-10.2]). This was not statistically significant. Children whose parents thought that

antibiotics would be of benefit were 1.6 times more likely to receive antibiotics than children whose parents expressed no opinion about the value of antibiotic therapy (OR 1.6[0.76-3.3]), although this was not statistically significant ( $p>0.05$ ).

**Table 17: Parent Factors and the Physician Antibiotic Prescribing Decision (N=209\*)**

| <i>Factor</i>  | <i>Reference</i> | <i>Odds Ratio<sup>1</sup></i> | <i>95% CI</i> | <i>P Value</i> |
|--|------------------|-------------------------------|---------------|----------------|
| <b><i>Parent Diagnosis</i></b>                       | No opinion       |                               |               | 0.25           |
| 1. Ear infection                                     |                  | 2.66                          | 0.69- 10.2    |                |
| 2. Other Illness                                     |                  | 3.49                          | 0.76- 16.01   |                |
| <b><i>Belief in Antibiotic Value<sup>1</sup></i></b> | No opinion       |                               |               | 0.15           |
| 1. Positive  |                  | 1.6                           | 0.76- 3.3     |                |
| 2. Negative  |                  | 0.31                          | 0.06-1.59     |                |

\*87 missing cases

<sup>1</sup> Odds ratios computed using multivariate logistic regression analysis, controlling for the effects of child's age, gender, symptoms of earache, fever, and ear pulling

- ***Parent Impression of Treatment Response in Previous AOM***

Sixty-five percent (196/296) of children diagnosed with AOM had a history of the disease (median number of previous episodes = 3). One hundred sixty-seven (85%) of these parents had consulted a physician and received a prescription for antibiotic therapy during a previous AOM episode. One hundred and thirty five (81%) of these parents believed that antibiotics had benefited their child, 20 parents (12%) had no opinion, and 12 parents (7%) thought the antibiotic provided no benefit. If their child was sick with a chronic illness such as leukemia (N=5), the parent was more protective of the child, and requested antibiotic therapy. If other siblings or children in the same day care were diagnosed with AOM, parents expected the same treatment for their child (N=28).

- ***Parents' Beliefs about the Value of Antibiotics in Current AOM***

Parents indicated whether they thought their child would benefit from antibiotic treatment at this medical visit. Of those children diagnosed with AOM, 125 parents (43%) answered in the

affirmative, 165 parents (55%) had no opinion and 6 parents (2 %) answered in the negative. When adjusted for the child’s symptoms, the parent belief in the value of antibiotics at this visit did not significantly influence the physician prescribing decision. [Table 17].

- ***Time of Presentation***

Parents who presented during evening and night time hours were no more likely to receive antibiotic therapy than parents who presented during the day (p=0.07).

### ***3.5.4. Potential Physician Factors contributing to the Physician Decision to Prescribe Immediate Antibiotic Therapy***

The contribution of selected physician factors to the physician antibiotic prescribing decision is quantified in Table 18. Physician factors investigated were those presented in the study Conceptual Framework (*Section 1.3*).

***Table 18:Physician Factors and the Antibiotic Prescribing Decision (N=228\*)***

| <b><i>Physician Factor</i></b>       | <b><i>Reference</i></b> | <b><i>Odds Ratio<sup>1</sup></i></b> | <b><i>95% CI</i></b> | <b><i>P value</i></b> |
|--------------------------------------|-------------------------|--------------------------------------|----------------------|-----------------------|
| <b><i>Part-time Work Status</i></b>  | Full –time              | 2.53                                 | 1.16- 5.6            | 0.02                  |
| <b><i>≥ 10 Years in Practice</i></b> | < 10 years ED practice  | 1.47                                 | 0.72- 3              | 0.3                   |

\*68 missing cases

<sup>1</sup>*Odds ratios computed using multivariate logistic regression analysis, controlling for the effects of child’s age, gender, symptoms of earache, fever, and ear pulling*

#### ***3.5.4.1. Physician Experience and Work Status***

The part-time physician group was two and a half times more likely to prescribe immediate antibiotic therapy for children diagnosed with AOM than the full-time physician group, after controlling for the effects of child’s age, gender and symptoms of earache, ear pulling and fever (OR 2.53[1.16-5.6]) (Table 18). Part-time physicians made treatment decisions in 114 (40%) of the study children diagnosed with AOM. Overall, 100 of 114 children (88%) diagnosed by part-time physicians were treated with immediate antibiotic therapy, 5 (4%) of the parents were given an

antibiotic prescription to fill at their own discretion, and 9 (7%) were given no specific follow up recommendation. The rate of antibiotic prescribing in this physician group ranged from 50% to 100% of all diagnosed cases (median 89%, mode 100%, range 50). The full-time physicians made treatment decisions in 168 (60%) of the study children diagnosed with AOM. Overall, 120 of the 168 (71%) children diagnosed with AOM were treated with immediate antibiotic therapy, 29 (17%) parents were given a prescription for antibiotics to fill at their own discretion, and 8 (5%) parents were given no specific follow-up recommendations. The rate of antibiotic prescribing in this physician group ranged from 46 to 100% (median 70%, mode 46%, range 54) of all diagnosed cases.

- ***Association between Diagnostic Certainty and Management Decision (N=163)***

Regardless of physician work status, there was a significant association between the diagnostic certainty rating recorded on the Clinical AOM Questionnaire and the prescribing decision ( $\chi^2$  55.46, df 39;  $p=0.04$ ). If the physician reported a high degree of certainty in the AOM diagnosis in the individual child, he/she was more likely to prescribe immediate antibiotic therapy. Conversely, if the physician felt less certain of the diagnosis, he/she was more likely to recommend expectant management.

- ***Physician Judgment of the Severity of Symptoms (N=163)***

In the 163 clinical encounters for which physician data was recorded, the physician judgment of the severity of the child's symptoms was significantly associated with the management decision ( $p=0.004$ ). In the 163 children for whom data was available, a child was 3 times more likely to receive antibiotic therapy if the physician thought that the symptoms were severe (OR 3.3 [1.5-7.4]), after controlling for child demographic and clinical factors. There was insufficient data to examine the association between particular otoscopic findings and the management decision.

- ***Influence of Perceived Parent Treatment Expectations (N=163)***

When asked in questionnaire format, 8 (30%) of 24 physicians estimated that, in the previous year, about 5% of their management decisions in AOM were altered by parents' treatment preferences (median 25%, inter-quartile range 25 [5-30]). All but one of the physician responses indicated that physician management decisions were changed by parents' treatment expectations in less than 40% of all diagnosed cases. The physician group estimated that approximately half of the parents diagnosed with AOM expressed a treatment preference. They believed that about 50% of all parents requested a prescription for antibiotics and 50% wished expectant management. When asked about the role of the parent in decision making, physicians responded that approximately half of the parents wanted the physician to make the treatment decision, a quarter wanted to be involved in the treatment discussion, and a quarter wanted to make the final decision. Most physicians stated that they were most comfortable making the treatment decision themselves, and less comfortable with the parent making the final decision.

In 12% of 163 AOM diagnoses, the treating physician indicated that his/her perception of the parents' treatment expectations had some influence on the prescribing decision. In actual clinical practice, 12 of the 24 study physicians demonstrated a slightly higher rate of antibiotic prescribing for AOM diagnosed children whose parent expressed a preference for antibiotic treatment compared to the baseline antibiotic prescribing rate (all 282 AOM cases) [Table 19]. In this circumstance, the median rate of antibiotic prescribing increased by 5% to 75% for the full-time physician group [range 57-80] and by 11% to 100% [range.8-1.0] for the part-time physician group. Fifteen physicians showed no change in the rate of antibiotic prescribing by parent treatment preference: 7 (47%) of these physicians were already treating 100% of AOM cases with antibiotics.

**Table 19: Proportion of AOM Diagnoses treated with Immediate Antibiotics**

| MD Status | Years in Practice <sup>1</sup> | # Diagnoses/MD <sup>2</sup> | All AOM Diagnoses                   | Parent expects Antibiotics for AOM  |
|-----------|--------------------------------|-----------------------------|-------------------------------------|-------------------------------------|
| N=24      | (Median, IQR)                  | (Median, IQR)               | Antibiotic Prescribing <sup>3</sup> | Antibiotic Prescribing <sup>4</sup> |
| Full-time | 10 [5-16]                      | 12 [6-14]                   | .70 [.46-1.0]                       | .75 [.67-1.0]                       |
| Part-time | 10 [7-15]                      | 3 [2-5]                     | .89 [ .50-1.0]                      | 1.0 [.8-1.0]                        |

<sup>1-2</sup> Median and Inter-quartile range values

<sup>3-4</sup> Median and range values

- **Awareness and Clinical Application of Scientific Evidence**

In the baseline questionnaire, the physician judgment of the otoscopic findings and the severity of clinical symptoms were consistently identified as the two most critical factors affecting the decision to prescribe immediate antibiotic therapy in the hypothetical clinical encounter.

Sixteen (67%) physicians indicated that their first choice of therapy for healthy children of all ages diagnosed with AOM was immediate antibiotic therapy. Physicians estimated the proportion of diagnoses in which they currently prescribe antibiotics (Table 20). Responses ranged from 20% of cases to 100 % (median 65%, mode 80%, inter-quartile range 40 [40-80]). When their estimated and actual antibiotic prescribing practices were compared, 6 of the 12 full time physicians underestimated their actual rate of antibiotic prescribing by at least 20%, while three overestimated by at least 20%. Two physicians showed large discrepancies between actual and estimated antibiotic prescribing (underestimates of 46% and 47%, respectively). There was not sufficient data to describe the part-time physician group.

**Table 20. Estimated and Actual Proportion of AOM Diagnoses Treated with Immediate Antibiotics, Full Time ED Physicians Only**

| <i>Physician ID</i> | <i>Actual Proportion of AOM Diagnoses Treated with Antibiotics</i> | <i>Estimated Proportion of AOM Diagnoses Treated with Antibiotics</i> | <i>Difference</i> |
|---------------------|--|---|-------------------|
| 1                   | 1.0  | 1.0   | 0                 |
| 2                   | .91  | .60   | +.31              |
| 3                   | .46  | .25   | +.21              |
| 4                   | .78  | .50   | +.38              |
| 5                   | .50  | .30   | +.2               |
| 6                   | .75  | .95   | -.2               |
| 7                   | .68  | .65   | -.3               |
| 8                   | .65  | .80   | -.15              |
| 9                   | .71  | .25   | +.46              |
| 10                  | .94  | 1.0   | -.6               |
| 11                  | .67  | .20   | +.47              |
| 12                  | .64  | .75   | -.11              |

Physicians also estimated the proportion of all AOM diagnoses in which they would be prepared to recommend expectant management. The full time physician estimated and actual rates of this treatment option are displayed in Table 21. Physician responses ranged from 0% of cases to 100% (median 40%, mode 25%, inter-quartile range 60 [25-85]). Three physicians would never be prepared to recommend a watch and wait approach, and four physicians said they would always recommend such an approach. No significant difference in physician response was noted for children less than and 2 or more years of age. Seventy-five percent of the physicians overestimated their willingness to recommend expectant management in the clinical encounter between 8 and 65%. A comparison of the second columns of Table 20 and 21 also reveal discrepancies in physician estimates of their rate of antibiotic prescribing and recommendation of watchful waiting.

**Table 18. Estimated and Actual Proportion of AOM Diagnoses treated with Expectant Management (WW), Full Time ED Physicians**

| <i>Physician ID</i> | <i>Actual Proportion of AOM<br/>Diagnoses treated with WW</i> | <i>Estimated Proportion of AOM<br/>Diagnoses treated with WW</i> | <i>Difference</i> |
|---------------------|---|--|-------------------|
| 1                   | 0   | 0  | 0                 |
| 2                   | .08   | .25  | -.17              |
| 3                   | .54   | .75  | -.21              |
| 4                   | .22   | 1.0  | +.12              |
| 5                   | .5  | .95  | -.45              |
| 6                   | .25   | .0   | +.25              |
| 7                   | .32   | .4   | -.08              |
| 8                   | .35   | 1.0  | -.65              |
| 9                   | .29   | .85  | -.56              |
| 10                  | .06   | 0  | +.06              |
| 11                  | .33   | .80  | -.47              |
| 12                  | .36   | .5   | -.14              |

Physician treatment decisions in seven hypothetical clinical vignettes were evaluated as a measure of practice variation in the department. In three of the 7 vignettes, there was little consistency in the treatment decision across the physician group. Probes which generated discrepant decisions included: red TM, low grade fever of variable duration ranging from 24 hours to 4 days, and history of recent upper respiratory tract infection. It is not clear whether or not the probes actually influenced practice decision, or whether the decision reflected “usual’ practice. It appeared that those physicians who estimated high antibiotic prescribing rates (>80%) were likely to treat, whereas those with lower estimated antibiotic prescribing rates were more variable in their responses. The practice variation did not appear to reflect differences in physician specialty. These

findings could alternately reflect inconsistency in diagnostic decision-making, as the physicians were not asked to justify their choice.

In order to determine the minimal clinically important difference to be tested in a randomized clinical trial, physicians were asked to indicate how similar expectant and antibiotic management had to be (measured by percentage treatment failure at one month) to be considered equivalent. Three options were provided and described using both absolute difference and NNT indices. Forty-six percent indicated that the margin of difference could be as large as 5% for the two to be considered equivalent. The remaining responses were equally divided between 2% and 10%.

When asked about their knowledge and clinical application of the results of a recently published meta-analysis on the management of AOM, 60% of the physicians responding to the questionnaire stated that they were not aware of the report. Of those aware of the paper, only four physicians stated that they would consider a change in their clinical practice on the basis of the published results. Fifteen of the 24 physicians indicated that further RCT evidence was required before they would consider a change in their current management of AOM. Twenty-three of the 24 physicians indicated that a department clinical practice guideline would aid the process of decision making with parents.

- ***Weighing the Risks and Benefits of Antibiotic Treatment***

In 90% of the 163 clinical encounters in which physicians completed an AOM Clinical Questionnaire, fear of potential complications from failure to treat was judged as an insignificant influence on the treatment decision. However, antibiotic therapy was prescribed in 78% of these children.

In the hypothetical clinical context, physicians' estimates of the risk of serious complications were inflated in comparison to the actual risk. Physicians were asked to estimate the probability that a

child diagnosed with AOM and not treated with antibiotics would develop complications of either mastoiditis or meningitis in Ottawa. Most physicians estimated the likelihood of mastoiditis at 5% (median 1%, range 0-5). The actual probability is approximately 0.2%<sup>76</sup>. Most physicians estimated the probability of meningitis at 1% (median 1%, range 0-10%). The actual likelihood of this complication is closer to 0.2 percent<sup>76</sup>. Despite these inflated risk estimates, 58% were only somewhat concerned about missing a bacterial infection that progresses to mastoiditis or meningitis if they recommend a watch and wait strategy. Twenty-five percent were not concerned about this possibility. All physicians stated that they were globally concerned about the increasing emergence of antibiotic-resistant bacteria and were making an effort to minimize antibiotic use in their practice. Eighty percent indicated that they were reconsidering their own antibiotic-prescribing behavior, reviewing the literature to increase their knowledge, and discussing the issue with their colleagues. Eighty percent indicated that they were starting to adopt a watch and wait approach to select cases, and seventy percent stated that they were trying to educate colleagues to reduce indiscriminate antibiotic prescribing.

- ***Influence of Medical Guidelines or Respected Clinical Leader***

In clinical practice, physicians identified the professional standard of practice as an important influence on the management decision in 86% of AOM diagnoses and the practice of a clinical leader as an important influence on their management decisions in 70% of cases.

- ***Environment (Acuity, Time)***

In clinical practice, physicians indicated that time constraints (i.e. not enough time to discuss diagnosis and treatment options) did not affect their management decision making in 63% of AOM diagnoses. However, in discussions with physicians the lack of time to explain therapeutic options was frequently identified as a rationale for antibiotic prescribing in AOM diagnoses.

**3.6 Objective 6: To describe the performance characteristics of the composite model predicting the physician antibiotic prescribing decision in children diagnosed with AOM**

The composite model predicting the physician antibiotic describing decision included the following variables, in addition to random error:

- *Child's Age*
- *Child's Gender*
- *Presence of Earache*
- *Presence of Fever*
- *Physician Work Status (Full time versus Part time)*

The performance characteristics of the composite model are displayed in Table 19. The overall accuracy was 61%. The model sensitivity was 58% ( $\pm 1.2\%$ ), specificity was 71% ( $\pm 3.5\%$ ), positive predictive value 88% ( $\pm 5\%$ ) and negative predictive value 31% ( $\pm 6\%$ ).

**Table 19: Performance Characteristics of Composite Model Predicting Physician Prescribing Decision (N=235\*)**

| <i>Predicted</i>        | <i>Observed</i>    |                         |              |
|-------------------------|--------------------|-------------------------|--------------|
|                         | <i>Antibiotics</i> | <i>Watch &amp; Wait</i> | <i>Total</i> |
| <i>Antibiotics</i>      | 108                | 14                      | 122          |
| <i>Watch &amp; Wait</i> | 78                 | 35                      | 113          |
| <i>Total</i>            | 186                | 49                      | 235          |

• *47 missing cases excluded from analysis*

• *Cut off value 0.8*

As in Section 3.4, a clinical scoring system was developed to predict a physician decision to prescribe antibiotics following a clinical diagnosis of AOM. Only empirical, reliable variables that significantly contributed to the prediction of antibiotic prescribing in the composite model were selected for inclusion in the clinical score. These were clinical variables of age ( $\leq$  or  $>$  2 years),

presence of earache and presence of fever. Gender did not contribute to prediction (beta coefficient 0.01). The physician variable was not included, as it was not considered a reliable marker of prediction. The clinical score was derived from a rounding of the integers of the beta coefficients in the logistic regression model. The probability of antibiotic prescribing given a clinical score was calculated from the median predicted value derived from the logistic regression model. This was compared to the observed value in the logistic regression model. A threshold clinical score value was arbitrarily selected to indicate a high and low probability of antibiotic prescribing decision.

**Table 23: Clinical Scoring System for Antibiotic Prescribing Decision in AOM**

| <i>Variable</i>     | <i>Reference Category</i> | <i>Beta Coefficient<sup>1</sup></i> | <i>Integer Score<sup>2</sup></i> |
|---------------------|---------------------------|-------------------------------------|----------------------------------|
| Age ≤2 years old    | >2 years                  | 0.832                               | 1                                |
| Presence of Fever   | No fever                  | 1.04                                | 1                                |
| Presence of earache | No earache                | 1.03                                | 1                                |

<sup>1</sup> Derived from multivariate logistic regression analysis model including variables of child's age, gender, earache, absence of fever.  
<sup>2</sup> Derived by multiplying beta coefficient by factor of 1

To test the scoring system, the predicted and observed probability of antibiotic prescribing in AOM diagnoses with various combinations of variables yielding different clinical scores were calculated. These are displayed in Table 24.

**Table 24: Observed and Predicted Antibiotic Prescribing in AOM Diagnoses**

| Variable Combination        | Clinical Score | N  | Observed Value | Median Predicted Value |
|-----------------------------|----------------|----|----------------|------------------------|
| No earache, no fever, age>2 | 0              | 4  | .25            | .46                    |
| No earache, no fever, age<2 | 1              | 15 | .60            | .66                    |
| No earache, fever, age >2   | 1              | 15 | .73            | .71                    |
| No earache, fever, age<2    | 2              | 48 | .88            | .85                    |
| Earache, fever, age>2       | 2              | 67 | .85            | .87                    |
| Earache, fever, age<2       | 3              | 28 | .91            | .94                    |

There is a positive correlation between the observed and predicted values (Spearman rho 0.94 (p=0.005). A cutoff value of 2 was selected to discriminate between children with AOM prescribed antibiotics and watchful waiting. The performance characteristics of the clinical scoring model are displayed in Table 25.

**Table 25: Classification Table using Clinical Scoring System, with cutoff value of 2 (N=177\*)**

| Predicted                  | Observed               |                  | Total |
|----------------------------|------------------------|------------------|-------|
|                            | Antibiotics Prescribed | Watchful Waiting |       |
| Score $\geq 2$ Antibiotics | 124                    | 19               | 143   |
| Score $< 2$ WW             | 21                     | 13               | 34    |
| Total                      | 145                    | 32               | 177   |

\* 105 missing cases excluded from analysis

The performance characteristics of the clinical scoring system are displayed in the above table. The model sensitivity was 86% ( $\pm 5\%$ ), specificity was 41% ( $\pm 7.2\%$ ), positive predictive value 87% ( $\pm 5\%$ ) and negative predictive value 38% ( $\pm 7.2\%$ ). Given that this model has fewer variables than the best fitting model described above and superior performance characteristics, the clinical scoring model is a better model than the full model outlined above (with cutoff value of 2) in predicting the physician antibiotic prescribing decision in this sample.

### **3.7 Objective 7: To describe Clinical and Functional Outcomes 48 Hours after Emergency Department Visit**

Six hundred and twenty-eight of 769 (82%) study participants, including 255 (86%) of children diagnosed with AOM, agreed to a telephone interview with the study investigator 48 hours after the emergency visit [See Study Flow Diagram, p.54]. Twenty-three (9%) of the AOM follow up interviews were conducted in the French language.

#### **3.7.1. Clinical Outcome at 48 Hours**

Eighty percent of the parents interviewed stated that their child was clinically improved at 48 hours after the ED visit (N=510; including 204 of 255 AOM diagnoses).

Two children initially diagnosed with viral illness/query AOM developed serious complications within 48 hours of the initial ED visit. In both cases, the initial diagnosis was uncertain. A seven-month old boy initially presented to the ED with a 48-hour history of fever and vomiting (Case 1). A diagnosis of AOM was given by the resident, and changed to viral illness by the attending physician. A prescription for antibiotics was given to the mother to fill at her discretion. The prescription was filled, but the child was unable to take the medication because of persistent vomiting. The child returned to the ED within 24 hours with a febrile seizure, and was diagnosed with meningitis. The child was admitted to hospital, and treated with a 10-day course of antibiotics. Audiology testing during the six months following this illness documented moderate hearing loss in both ears.

A 12 year old girl with no history of ear infections presented initially with a 48 hours history of ear pain, fever and sore throat (Case 2). She was diagnosed with a viral illness and sent home with medicine to control fever. Her condition deteriorated progressively over the next 48 hours, and on return to the ED, was diagnosed with mastoiditis. She was admitted to hospital, and treated with a

10-day course of intravenous antibiotics. Her diagnosis was reviewed and changed to a viral glaucous bullous myringitis by the otolaryngologist. There was no follow up information available in the medical chart at the time of writing.

A third study child (Case 3) was diagnosed with mastoiditis at the initial ED visit. This 30-month old female had a 48 hours history of ear pulling, fever and cold symptoms. She was admitted to hospital, treated with myringotomy and intravenous antibiotics. Audiology testing at six months after the illness documented normal hearing.

### ***3.7.2. Parental Perception of Diagnosis and Treatment Recommendation***

All parents except one mother with limited English were aware of the clinical diagnosis and treatment recommended by the ER physician.

### ***3.7.3. Parents' Adherence to Recommended Treatment***

All parents except 8 stated that they had no difficulty administering the prescribed antibiotics. Many parents commented that their children liked the banana flavor of the Amoxicillin. The mother of Case 1 (p 89) had difficulty administering the antibiotic because of persistent vomiting. Seven parents commented that their child experienced gastrointestinal side effects with Pediazole.

Twenty-four percent (7/29) of parents given an antibiotic prescription filled it within 24-48 hours of the emergency room visit because the child's symptoms were not improving. Those parents who did not need to fill the prescription commented that they appreciated the option of no antibiotics, and were happy that their child did not require this therapy.

### ***3.7.4. Parental Satisfaction with the Treatment Decision and Decision-Making Process***

Two hundred thirty (90%) interviewed parents of children diagnosed with AOM were satisfied with the treatment decision and with their involvement in the treatment decision. Ninety percent of these parents (N=207) reported a discussion of the diagnosis and possible treatment modalities for their

child with the physician. Five parents noted that the physician allowed them to view the middle ear with the otoscope. The majority of parents with particular treatment preferences felt listened to by the doctor. However, 25 parents reported that the physician talked to the resident rather than to them or merely informed them of the treatment decision with little discussion of alternatives or the rationale for the treatment decision. Six parents stated that they received discrepant information from the resident and the staff physician with regards to recommended treatment. This caused confusion regarding the nature and severity of their child's illness, and a questioning of the validity of the diagnosis and competence of the physicians.

#### ***3.7.6. Consultation with Other Health Care Providers in the 48 Hours after the ER Visit***

Twenty-two percent (142/628) of parents interviewed reported that they consulted a second physician following the ER visit. Fifty-four parents of 255 (22%) children diagnosed with otitis media consulted a second physician within 48 hours of the ER visit. Fifteen of these 54 children (28%) received antibiotic therapy at the second medical consultation.

#### ***3.7.7. Impact of the Illness on the Family***

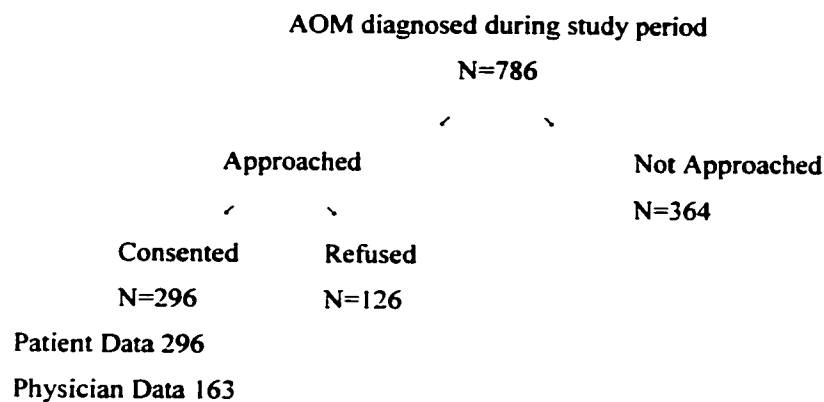
Thirty-five percent of children of school age missed one (25%) or 2 (10%) days of school or daycare because of the clinical illness. A similar percentage of parents missed one and two days of work.

### ***3.8 External Validity of Study Findings***

***3.8.1.*** During the study period, a total of 786 children were diagnosed with AOM in the ED. Four hundred twenty two of these children were screened and invited to participate in the study. Two hundred and ninety-six (40%) of these children participated in the study. One hundred and twenty-six other children had been identified as potentially eligible study candidates by the registration clerks, but their parents declined to participate in the study (N=126). This cohort included 19 parents who were unable to read English or French and 2 parents who resided outside of the Ottawa

region. Three hundred and sixty-four children were not approached about participating in the study. These children were identified through retrospective review of all Emergency Medical Consultation Records completed during the study period [See Flow Diagram 3.1.2.2. Data pertaining to the child's age, gender, symptoms, ED arrival time, and physician diagnostic and treatment decisions were extracted from the emergency record. No parent information was obtained for this group of children. The two groups of children diagnosed with AOM were compared to determine the external validity of the study sample.

**3.1.2.2. Flow Diagram of Children diagnosed with AOM in study period**



***Representativeness of the Study Cohort***

Study children diagnosed with AOM (N=296) differed significantly from the AOM group not enrolled in the study (N=364) with respect to age (p<0.01) and presenting symptom (p<0.01). Study children were more likely to be over the age of two years and present with ear pain. Members of the retrospectively identified cohort were more likely to be less than 2 years old and present with non-specific symptoms of fever and sleep disturbance.

## **CHAPTER 4**

### **Discussion**

#### ***4.1 Conclusions***

The overall objective of this study was to increase understanding of the process of parent and physician decision making in the context of a prevalent, acute but not life-threatening childhood illness, acute otitis media (AOM). A prospectively identified cohort of 769 parents and their children presenting to the ED with symptoms associated with and/or a parent suspicion of an ear infection were examined to address the three main study objectives:

1. To describe factors contributing to the parent decision to seek medical consultation for suspected AOM in the ED
2. To describe factors contributing to the physician decision to diagnose AOM, and
3. To describe factors contributing to the physician decision to prescribe immediate antibiotics following a clinical diagnosis of AOM.

The *main study findings* were as follows:

##### ***4.1.1. Parent Decision to Consult ED***

Study parents consulted the ED when they needed medical interpretation of the meaning of their children's symptoms (e.g. diagnosis), and guidance or medical intervention (e.g. antibiotics) with the management of these symptoms. Parents of those children diagnosed with AOM were more likely than parents of children diagnosed with other illness (OI) to present to the ED for symptom management when their usual health care resources were not available. Eighty percent of the parents of children diagnosed with AOM consulted the ED during evening or nighttime hours.

In follow-up telephone interviews, most parents indicated that they preferred to consult their own physician because this individual knew their child best, had established a trusting rapport with the child and parent, and was available for follow up of the child's condition as necessary. These parents elected to consult the ED because they believed their child's symptoms required immediate evaluation and intervention. If the child's symptoms were first noticed (especially for those children at day care or school) or judged as severe during the early evening hours, many parents indicated that they first considered consulting a neighborhood clinic for diagnosis or medical intervention. This decision was primarily determined by convenience (location and short waiting time to see the physician). After the closing time of the neighborhood clinics (2200 hours), if the parent thought that the child's symptoms were causing so much distress that the child would not sleep through the night, or his/her condition would significantly worsen over the night, the parent would consult the ED. Parents of some infants and toddlers only realized that their child was unwell when he/she suddenly awakened from sleep, screaming in what appeared to be severe pain of unknown origin; hence the increased ED consultation near midnight. A proportion of parents who had previously consulted the ED was aware of the telephone health line (exact numbers not available), had called for advice, and had been told to bring the child for evaluation. Most parents who had previously consulted the ED were aware of the potentially protracted waiting time, and believed that their child's symptoms justified the wait. Other parents who were not aware of the waiting time stated that in the future they would elect to give their child analgesia and consult their own physician in the morning.

These conclusions reflect the judgments of the study parents who agreed to participate in the study. Non-participants consulting the ED may have done so for different reasons.

#### ***4.1.2. Physician Diagnostic Decision***

Two hundred and ninety-six (38%) of the 769 study children were diagnosed with AOM. Four hundred seventy-three children were diagnosed with another illness; either viral illness, upper respiratory illness, gastroenteritis or asthma.

#### ***Factors contributing to the Physician Diagnostic Decision***

Bivariate and multivariate logistic regression analysis of selected child, parent and physician factors presented in the literature review identified the following as significant factors affecting the physician diagnostic decision of AOM:

- *Child's age and gender*
- *Presence of earache*
- *Absence of fever*
- *Parent Suspicion that child has an ear infection*
- *Parent belief that antibiotic therapy will benefit child, as compared to no opinion*
- *Examining physician working part-time basis in ED*

Each factor identified as a significant predictor of the physician diagnosis of AOM is discussed in the following section:

- ***Child's Age***

When age was considered alone, children over the age of 2 years were 53% more likely to be diagnosed with AOM than children  $\leq$  2 years old [1.14-2.16]. Two factors may explain the higher likelihood of AOM diagnosis in older children. First, most children over 2 years are sufficiently verbal to describe their symptoms. They are able to express a

complaint of pain and localize it to their ear(s). In a preverbal child, it is much more difficult to pinpoint the precise nature of the child's complaint. Ear pain is a powerful clue to the diagnosis of AOM. Ninety-six percent of study physicians listed ear pain as the diagnostic symptom critical to the diagnosis of AOM in children over 2 years of age. Secondly, children over 2 years of age are more likely to have previously experienced an episode of AOM. Teele <sup>4</sup>, in a longitudinal cohort study of children to three years of age, found that 62% of children had been diagnosed with one episode of AOM by their first birthday, and 17% of these children with at least 3 episodes. By the time these children had reached their third birthday, 80% of the cohort had been diagnosed with AOM at least once, and 46% had been diagnosed at least three times. The peak age-specific attack rate occurs between 6 and 18 months of age in otherwise healthy children. The frequent occurrences in this age group is in part a reflection of the fact that the eustachian tube of the young child is shorter, wider, straighter and more horizontal than that of the older child. Thus, organisms from the nasopharynx reach the middle ear more readily than they do in older children. By three years of age, the incidence of AOM decreases because of changes in the anatomy and physiology and maturing immune mechanisms<sup>8</sup>. Epidemiological surveillance data recorded in the United States (Cleveland, Ohio; Huntsville, Alabama; Galveston Texas), Finland and Sweden show that children may be categorized into three groups of approximately equal size relative to acute infections of the middle ear by 3 years of age<sup>82-84</sup>. One group is free of ear infections, a second group may have occasional episodes of AOM, usually associated with infections of the respiratory tract, and a third group is otitis-prone, subject to repeated episodes of acute infections. Parents whose children have previously been diagnosed with AOM are more

likely to equate current symptoms with those in previous AOM episodes, and emphasize the presence of these symptoms in their verbal account of the child's problem to the ED physician. The parent history may affect the initial diagnostic possibilities entertained, and in turn influence the data collected to either confirm or refute the diagnosis.

Children over the age of 2 years and diagnosed with AOM were over-represented in the study cohort, when compared to the age distribution of all children diagnosed with AOM in the study period. Both the verbalization of ear pain, and the similarity of the child's symptoms with those present during previous medical diagnosis of AOM, likely influenced parents' suspicion that their child had an ear infection. Parents who suspected an ear infection may have been more likely to enroll in the study when invited by the ED registration clerks.

However, in the composite model, controlling for the effects of type and duration of symptom, previous history, parent diagnostic suspicion, and physician work status, the age of the child no longer significantly contributed to the diagnostic decision. It may be that the physical symptoms in conjunction with the otoscopic findings, which were not evaluated in this study, predicted the physician diagnosis regardless of the age of the child.

### ***Parent or Child-Reported Symptoms***

Pediatric infectious disease textbooks state that children diagnosed with AOM may present with nonspecific signs and symptoms, including fever, irritability, headache, apathy, decreased appetite, vomiting and diarrhea<sup>8-12</sup>. Clinical findings of respiratory viral infection, including cough and nasal congestion, may frequently precede the specific signs of ear infection.

In the study cohort, parent or child-reported symptoms that significantly predicted a medical diagnosis of AOM were the presence of earache or the absence of fever, after controlling for the effects of age, gender and other study symptoms.

- ***Presence of Ear Pain***

Study children presenting with ear pain were 7.9 times more likely to be diagnosed with AOM than study children without no ear pain [5.2-12.1], regardless of age, gender and the presence of other symptoms (such as ear pulling). This symptom was the most significant predictor of an AOM diagnosis. Approximately 30% of the study children diagnosed with AOM had no ear pain. Niemela<sup>37</sup> also recorded a strong association between ear pain and AOM diagnosis. In his cohort of 354 children, those over 2 years were 8 times more likely to be diagnosed with AOM than URI in the presence of ear pain [4.8-15]. Those children under 2 years were almost 10 times [2.8-34] more likely to be diagnosed with AOM over URI in the presence of ear pain. Niemela<sup>37</sup> reported univariate analyses without controlling for the effects of child's age, which likely affects the elicitation of ear pain. Hayden and Schwartz<sup>85</sup> identified the presence of ear pain in approximately 80% of 355 consecutively diagnosed episodes of AOM.

The presence of ear pain in young children may be differentially labeled as unexplained fussiness or irritability, excessive crying or sleep disturbance, depending on the parent's subjective interpretation of the child's behavior. In this study, no operational definitions were given to parents, and it is not possible to know how different parents reported symptoms of ear pain, irritability, sleep disturbance and ear pulling, particularly in preverbal children. Therefore, the findings represent how parents subjectively described their children's symptoms. Other diagnoses recorded in children presenting with ear pain

included teething, foreign body or impacted wax in the ear, pharyngitis (referred pain from sore throat), viral illness (referred pain from nasal obstruction and sore throat) and constipation (Emergency Medical Consultation Record). Ear pain may also be associated with infections of the tonsils, adenoids, teeth, nasopharynx, larynx, and tumours in those regions that refer pain to the opposite ear along the tenth cranial nerve<sup>8</sup>.

While ear pain suggests the presence of fluid in the middle ear (increased pressure in an enclosed space), its presence does not inform the physician about the nature or composition of the fluid (e.g. sterile or pathological). The composition, which is evaluated only by tympanocentesis and culture, serves more as an aid to the treatment decision. The presence of ear pain may serve as a strong diagnostic clue to the examining physician. However, it may be that the actual diagnosis of AOM relies on the presence of certain otoscopic findings in conjunction with this physical sign, rather than ear pain alone. This association was not addressed in the current investigation.

- ***Absence of Fever***

Contrary to expectations, in this study the absence of fever significantly predicted a clinical diagnosis of AOM. Children presenting with fever were more likely to be diagnosed with other illness (OR 0.79 [0.45-0.99]) after adjusting for age and other symptoms. This group of children tended to undergo more laboratory investigations, including throat swab, urine culture, and in some cases, chest radiography and blood culture. It seemed that the presence of fever was a cue to more systemic illness, and further information was required for the physician to render a diagnosis. It may be that this is a spurious finding, and that if all children underwent similar investigations, there would be no association between fever and other illness.

In this study, parent report rather than an empirical measurement served as the indicator for the presence of fever. This choice of symptom definition likely introduced measurement error, which in turn may have contributed to the described relationship between fever and diagnosis in this study.

Similar to this study, Niemela<sup>37</sup> reported an inverse relationship between fever and AOM diagnosis in children over 2 years old (OR 0.5[0.3-0.9]). The presence of a fever has figured prominently in medical writings describing diagnostic criteria for AOM. Klein<sup>8</sup> states that fever is present in one-third to two-thirds of all children diagnosed with AOM. Ninety-six per cent of the ED physicians listed the presence of fever (not in itself defined) as critical to the diagnosis of AOM in children less than 2 years. Fifty percent of the study physicians listed fever as critical to the diagnosis in children over 2 years.

Fever was the most frequently reported symptom, with 68% of all study children reported to have a fever at the time of ED consultation or within hours of presentation. Although fever was defined as a rectal temperature over 38.5 C, in practice children were enrolled in the study if the parent stated that the child had a fever. It may be that a parent report of fever triggered registration clerks to recruit parents and their children into the study, regardless of the parent diagnostic suspicion.

Therefore, the parent impression rather than an objective measure was used to gauge the magnitude of association between symptom and disease. Ipp and Jaffe<sup>36</sup>, and Kramer<sup>26</sup> showed that the definition of fever varies among people, including physicians, regardless of educational status. All children did have temperatures recorded at the time of consultation, but these were not entered into the study database. The severity of fever was also likely affected by whether or not the parent had administered antipyretic medication,

and the timing of the medication in relation to the ED presentation. This suggests that it may not be fever in itself that is important in other studies, but an additional physical sign in conjunction with fever, or an otoscopic finding that determines the diagnostic decision. Of note, 153 study children presented with both ear pain and fever and 95 (62%) were diagnosed with AOM; 58 (38%) with other illness.

- ***Presence of Ear Pulling***

Study children whose parents reported the presence of ear pulling were twice as likely to be diagnosed with AOM than parents who did not note this sign, regardless of age category, gender or other symptoms (OR 1.8[1.8-2.8]). Although one might expect that ear pulling would be described with greater frequency among preverbal children, its frequency was slightly higher in children over the age of two years. Ear pulling and ear pain were likely correlated, as when both were considered, ear pulling was no longer a significant predictor of an AOM diagnosis.

Niemela<sup>37</sup> investigated the association between ear rubbing and AOM. It is not clear whether ear pulling and ear rubbing reflect the same behavioral sign. Other studies report ear tugging and feeling of blocked ear, which may be the antecedent to ear pulling. Ambiguity in symptom definition across studies makes comparisons tentative. The sensation of blocked ear was not explicitly addressed in this study, and parents did not volunteer such terminology when describing their children's symptoms. Nevertheless, Niemela<sup>37</sup> reported that children presenting with ear rubbing were 4 times more likely to be diagnosed with AOM compared to URI than children without ear rubbing [2-8.7]. The magnitude of the association did not differ by age.

A description of ear pulling, tugging or rubbing is useful when distinguishing whether or not it signals middle ear pathology. The frequency, nature, and laterality of the behavior may differentially suggest playfulness, discovery of the ear in a young child, or the presence of a foreign body, or pain. Clues as to whether ear pulling signals pathology or playfulness may be whether or not it is unilateral or bilateral, or increased with positioning horizontal (more pressure and presumed middle ear pain) versus upright<sup>5</sup>.

- ***Presence of Sleep Disturbance***

Study children whose parents reported acute sleep disturbance were twice as likely to be diagnosed with AOM than those children whose parents did not report this symptom, after controlling for child's age, gender and presence of other study symptoms. Sleep disturbance was not operationally defined, but rather reflects parents' subjective interpretation of the child's behavior. In the follow up telephone interviews, many parents described their child's disease presentation as one in which the child awoke suddenly from sleep, crying in pain. They were unable to console the child, and could not distinguish the cause of the crying. The sleep disturbance in AOM referred to disruption during the night of the consultation rather than the previous night. Several physicians noted that such a parent description served as an important clue to the diagnosis of AOM. Medical writings suggest that increased pressure in the middle ear arising from the presence of fluid induce pain that increases when the child is positioned in the horizontal position. The pain in the ear leads to the sudden disturbance in sleep<sup>8</sup>.

In the composite model, the presence of sleep disturbance failed to significantly predict the physician diagnostic decision.

Parents did not report the presence of combinations of symptoms, and therefore any attempt to examine the relationship between symptoms in combination (i.e. ear pain and fever) and diagnosis is subject to error. The frequencies of symptom combinations (as extrapolated from the data) were small and therefore not examined.

- ***Parent Suspicion of an Ear infection***

The children of parents who suspected an ear infection were four times as likely to be diagnosed with AOM compared to the children whose parents expressed no opinion about the nature of their child's illness (OR 3.59 [1.93-6.7]). This finding was regardless of the age, gender, type and duration of the child's symptoms, and whether the parent thought antibiotics would benefit the child. Conversely, the children of parents who suspected other illness were half as likely to be diagnosed with AOM than children of parents with no diagnostic opinion, though this did not reach statistical significance. This suggests that the parent may selectively tailor the history to guide the physician to a diagnosis of AOM, or that the parent is correctly interpreting the child's symptoms, based on parent's familiarity with these symptoms in previous AOM episodes.

- ***Parent thinks antibiotic will benefit child today***

In the study, the children of parents who expressed a belief that antibiotics would be of benefit were two and a half times as likely to be diagnosed with AOM than children whose parents had no opinion (OR 2.47 [1.6-3.9]). This finding was noted after controlling for the effects of previous illness experience and parent diagnostic suspicion. Vinson and Lutz<sup>42</sup> concluded that diagnostic decision making might be driven by parent treatment expectations in selected cases, especially when the physician is uncertain about the diagnosis. They suggested that a physician might search for a diagnostic label that fits

the parent expectation in these uncertain cases. In this study, physicians were relatively certain of the diagnostic label in cases for which this data is available, suggesting that this was not the case in this study. The reason for this finding is not clear from the study data.

- ***Examining physician***

Given that the examining physician makes the diagnostic decision, it seems reasonable to expect that certain physician characteristics would significantly predict the clinical diagnostic decision. In this cohort, a child examined by a physician providing part time clinical service was twice as likely to be given a clinical diagnosis of AOM than a child examined by a full time ED physician (OR 2.01[1.3-3.1]). This relationship was found after controlling for the effects of the age, gender, type and duration of the child's symptoms, previous AOM, and parent diagnostic suspicion. Both physician groups made diagnostic decisions in approximately equal proportions of study children (PT 40% of study cohort, FT 60% of study children). Part-time physicians were more likely to work during the evening and night hours. As there is no gold standard criterion for the diagnosis, it is not possible to establish the validity of the physician diagnosis. One cannot assume that the difference in the two physician groups implies over diagnosis of AOM by part-time physicians and valid diagnosis by the full time group.

The basis for the recorded differences between the groups of full time and part time physicians is not clear. The two groups did not significantly differ with respect to AOM diagnostic criteria. Both groups appeared to distinguish AOM from other illness based on the presence of fever and ear pain, and otoscopic findings of a red, bulging TM with loss of landmarks. Despite these similarities, it is not possible to assess group differences with respect to the clinical application of these criteria. Physician groups have shown

differences between what they say they would do in hypothetical encounters and in actual clinical practice<sup>70-72</sup>. Also, the level of agreement in subjective interpretation of the diagnostic criteria between the two physician groups is not known. What one group describes as a fever or a bulging TM may not be labeled as such by the other group of physicians. This state may also occur within the two groups, such that there is considerable imprecision in measurement among physicians. However, the diagnostic certainty ratings of AOM diagnoses did not significantly differ by physician group.

Differences in years in practice did not explain the differences in diagnostic decision making. No information was obtained about the physician's involvement in continuing education workshops to update knowledge about diagnosis etc.

Differences in the likelihood of AOM diagnosis may reflect group differences in expectations about the spectrum of disease. As PT physicians also provide clinical service in the community, one might conjecture that the spectrum of AOM that they see and diagnose is systematically different than the disease spectrum seen by FT ED physicians. There is no data to support or refute this hypothesis. Some physicians assert that children presenting with symptoms of AOM in a ED are "sicker" than those children presenting with similar symptoms in a community physician office. Others suggest that it is not the disease presentation, but the time of presentation that determines the place of medical consultation<sup>56</sup>. It is known that AOM accounts for a larger proportion of all diagnoses in community practice than in ED practice<sup>2</sup> and therefore perhaps, a PT physician may expect to diagnose AOM more readily than does a ED physician. This would follow from the representative and availability heuristics discussed in *Section 1.2.2.4*. Full time ED physicians do not preferentially look for AOM, as this diagnosis

accounts for only about 6% of total ED practice, compared to 40% of community practice. This raises the issue of which group is making the correct diagnosis if the presenting children do not appreciably differ.

Some clinicians and researchers have suggested that physicians over-diagnose AOM, since there is no commonly employed objective diagnostic standard to aid diagnosis<sup>16-20</sup>. This may reflect differences in “comfort zone” between physician groups<sup>70-72, 86</sup>. Again, this is conjecture and clearly an area for further investigation. ED physicians practice within a paradigm of urgent care. They are charged with the responsibility to provide accurate diagnosis and stabilization of the child needing urgent care. Long-term follow-up issues are generally the responsibility of other physician groups. In contrast, the PT physician, who also works in the community, may practice in a different paradigm that emphasizes a preventive, long-term care approach, even when practicing in the tertiary care ED setting. Different comfort levels regarding missing a diagnosis when it is in fact present versus over diagnosis may operate in the two groups based on their usual mode of practice. For example, in the community setting, a PT physician may not diagnose AOM in a child if unsure, because he knows that the parent will re-consult if the child does not improve because of the rapport and follow up mechanism inherent in community practice. However, in the ED setting where no follow up mechanism is ensured and the physician does not know the child or parent, he may be more likely to make a diagnosis, given the same clinical findings. This consideration may not factor significantly in the decision making process for the FT ED physician.

### ***Physician Antibiotic Prescribing Decision***

Two hundred and twenty-one (78%) of 282 evaluable study children diagnosed with AOM (14 missing information about physician treatment decision) were treated with immediate antibiotic therapy by the attending ED physician. Parents of 58 children (22%) were advised to monitor the child's symptoms; 31 (12%) of the 58 parents were given a prescription for antibiotics to fill at their discretion if they thought that their child's condition was failing to improve. The age of the child did not significantly influence the treatment decision. Eighty-four percent of children  $\leq 2$  years old were treated with immediate antibiotic therapy compared to 75% of the children over the age of 2 years.

#### ***4.1.1.1. Factors contributing to the Physician Decision to Prescribe Antibiotics in Children Diagnosed with AOM***

Bivariate and multivariate logistic regression analysis of selected child, parent and physician factors presented in the study conceptual framework (and extracted from the literature), identified the following factors as significant predictors of the physician antibiotic prescribing decision in children diagnosed with AOM:

- *Presence of Earache*
- *Presence of Fever*
- *Physician Work Status*

*Overall, these three factors correctly predicted the treatment decision in 79% of AOM diagnoses.* Each factor identified as a significant predictor of the physician antibiotic prescribing decision is discussed in the following section.

- ***Presence of Ear Pain***

Study children diagnosed with AOM who presented with ear pain were 3.5 times more likely to be treated with antibiotics, regardless of age, gender, other symptoms, symptom duration and examining physician, compared to children with no ear pain (OR 3.45 [1.4-8.6]). Although there is no strong scientific evidence to support the use of antibiotics, some physicians may believe that antibiotics provide some therapeutic advantage over expectant management. A meta-analysis<sup>59</sup> showed those children treated with antibiotics experienced a shorter duration of ear pain compared to children given placebo. The equivalency of adequate analgesia and antibiotic therapy has not been established, such that physicians may feel that antibiotics are the only useful tools and the parent and child need some medical intervention. Some ED physicians hypothesized that ear pain may suggest acute infection that needs to be treated with antibiotics, as opposed to a serous otitis that does not need acute treatment. Several physicians interviewed in a post-hoc interview suggested that ear pain was associated with significant otoscopic findings (personal communication), though study data is not available to confirm this hypothesis. Gonzalez-Vallejo<sup>56</sup> showed that the variables related to the physical examination (clinical and otoscopic) were the most significant predictors of antibiotic prescribing in their physician sample. These study findings were based on physician treatment decisions in hypothetical rather than actual clinical situations

- ***Presence of Fever***

Irrespective of the child's age, gender, other symptoms, symptoms duration and examining physician, children diagnosed with AOM who presented with fever were 3 times more likely to be treated with immediate antibiotics than children without fever

(OR 3.0; [1.5-6.1]). The absence of fever significantly predicted an AOM diagnosis, but once diagnosed, the presence of fever appeared to influence the treatment decision. This finding suggests that it is not fever alone, but likely the association with other factors, including otoscopic findings, that influences both physician decisions. The scientific basis for this decision is not clear, but may reflect physician suspicion of a bacterial infection, or superimposed bacterial infection on a viral illness, or potentially more severe illness. This belief was supported in individual discussions with a group of ED and infectious disease physicians following data analysis<sup>47-49</sup>. However, certain viral illnesses also present with fever, so this supposition needs further study. It may be that children with fever had different otoscopic findings that influenced prescribing decision, rather than simply the presence of fever.

- ***Physician Work Status***

Physicians providing part time clinical service in the ED were 2.5 times more likely to prescribe immediate antibiotics following a diagnosis of AOM than full time ED physicians, after controlling for the effects of child age, gender, symptom presentation and duration (OR 2.53; [1.2-5.6]). The reason for the difference in prescribing pattern is not clear from the data. Forty percent (6/15) of PT physicians compared to 8% (1/12) of FT physicians prescribed antibiotics in 100% of their AOM diagnoses, respectively.

One may hypothesize that the treatment decisions made by part time physicians in the ED, to some extent, reflects their practice in the community. Pennie<sup>2</sup> reported that community physicians treated 97% of children diagnosed with AOM with immediate antibiotics. Although this survey data may not represent community practice in the entire province, the results suggest that antibiotic prescribing rates in the community are high,

relative to what might be expected if 80% of all AOM diagnoses are truly of viral etiology and resolve without treatment. Medical teaching continues to state that the first choice of treatment for AOM is antibiotic therapy<sup>5,65-67</sup>. High rates of antibiotic prescribing may reflect traditional practice patterns in busy office practices where the patient load limits the time available for discussion of treatment options and potential side effects. Parent treatment expectations also may play a greater role in the community physician treatment decision. If a child has a history of AOM successfully treated with antibiotics, a parent may expect her family physician to recommend the same treatment modality in all future AOM episodes. Conversely, lower rates of immediate antibiotic prescribing might be expected in a community setting than the ED because the physician, parent and child know and trust each other's judgment, and there is a built-in follow-up mechanism should the child's condition fail to improve.

The increased likelihood of antibiotic prescribing by PT compared to FT physicians may reflect differences in the level of comfort practicing in the ED setting. The prevalence and spectrum of disease seen in each practice setting may influence prescribing behavior. Though there is no data yet to support this supposition, community physicians may encounter a broader spectrum of AOM disease. The AOM cases that they diagnose in the ED setting may appear more severe than their average case, and in turn lead them to prescribe immediate antibiotic therapy. Also, part time physicians may more readily err on the side of caution and prescribe when in the ED setting because their usual follow-up mechanism is not assured. Full time physicians may see a narrow spectrum of AOM compared to community physicians. Relative to their entire clinical practice, AOM may be considered a benign illness. Full time physicians may feel that their failure to treat is

unlikely to lead to a serious complication, relative to other illnesses they encounter in their practice, and be more willing to recommend expectant management.

Part time physicians were more likely than full time ED physicians to practice during the evening and night. Some parents and physicians may perceive a need to initiate some form of active treatment, because of the perceived urgent nature of the presentation and the child's condition (e.g. severe pain). Although theoretically plausible, the study data suggests that the time of presentation did not affect the rate of antibiotic prescribing, and therefore does not explain the differences between physician groups.

- ***Current Antibiotic Prescribing Practice***

Study physicians consistently underestimated their actual rate of antibiotic prescribing. Awareness of the study may have influenced physician estimates of their current practice. This phenomenon has been previously described, and is known as the Hawthorne effect<sup>87</sup>. This bias suggests that physicians might consciously influenced their self-appraisals on the written questionnaire, given that the study examined treatment decisions in the context of growing concern over inappropriate use of antibiotics. The presence of the study may have also affected antibiotic prescribing practice as the actual rate of antibiotic prescribing was significantly lower for study children diagnosed with AOM than the group of children diagnosed with AOM who were not enrolled in the study.

- ***Attitude to Expectant Management***

There was a significant relationship between estimation and actual recommendations of watchful waiting – though study physicians consistently overestimated the proportion of actual recommendations. The propensity to overestimate expectant management and underestimate antibiotic prescribing in actual practice may be a result of the physician

awareness of the study. As noted in the previous section, physicians may have suspected that their antibiotic prescribing practices were being monitored, and consequently adjusted their estimations of their current practice accordingly. Some physicians showed discrepancy between their estimations of antibiotic prescribing and recommendations of expectant management. This is not easily explained, and requires discussion with the physician groups to identify possible reasons for this finding. The mismatch between estimated and actual practice suggests that intervention to stimulate practice change first needs to provide physicians with an accurate picture of their current practice. Direct feedback of the data to the physicians may be the first step in their critical appraisal of their practice.

### ***Other Interesting Findings***

- ***Child's Age***

In this study, the child's age was not associated with the treatment decision. This was surprising, as the age of the child emerged as an important factor in individual discussions with physicians at the time of questionnaire development and in published reports<sup>3</sup>. A proportion of the physicians interviewed prior to the study said that they were more cautious in children under two years of age, and therefore more likely to prescribe antibiotic therapy in similar cases to younger children. This did not appear to be the case in this physician group. It may be that study physicians thought that parents who brought their child to an ED believed their children were sicker than those parents who presented to a family physician office, and in turn, expected some form of medical intervention, regardless of the child's age. However, this finding may also reflect the age distribution of the children in the study. Those children diagnosed with AOM but not enrolled in the

study were more likely to be less than 2 years of age. In this retrospectively identified cohort, 88% of the children were treated with immediate antibiotic therapy.

- ***Duration of Symptoms***

The duration of the child's symptoms ( $\leq$  or  $>$  48 hours) did not significantly affect the treatment decision (OR 1.2;[0.5-2.7]). Although the literature and medical guidelines suggest that expectant management may be appropriate when clinical symptoms are present for  $\leq$ 48 hours, some physicians in the study recommended expectant management when symptoms were present over 48 hours. Other physicians prescribed antibiotic therapy without regard for the duration of symptoms. It may be that the number of children prescribed expectant management was too small to adequately detect significant differences.

- ***Time of Day of ED Consultation***

Children diagnosed during the night were no more likely to be treated with antibiotics than children diagnosed during the day. This is an interesting finding, as many of the parents presenting during the night did so because they thought they could not manage the child through the night. Parents whose children improved with pain medication alone (acetaminophen and codeine) expressed surprise and satisfaction with its effect, especially on pain and irritability. Anecdotally, some physicians expected children presenting during the night to be more likely to receive antibiotic therapy than children presenting during the day.

- ***Parent Belief in the Value of Antibiotic Therapy***

There was no statistically significant relationship between parent treatment expectation (as recorded on the parent survey) and the physician treatment decision. The degree to

which parents directly expressed a treatment preference to the attending physician is not known. Given that antibiotic therapy was believed to be so beneficial, few parents identified a preference for a wait and watch approach. Those parents who voiced a preference for a watch and wait approach in telephone interviews often stated that they were concerned about the rise in antibiotic resistant bacteria, and the potential future impact on the health of their child. This awareness had been generated by television and lay magazine reports about "flesh-eating" disease and "superbugs". These fears were often mentioned by women who preferred to use a form of alternative medicine e.g. homeopathy and chiropractic therapy for ear infections.

Anecdotally, some physicians indicated that they would be more likely to prescribe antibiotics in conditions of diagnostic uncertainty if requested by the parent. However, the same physicians would not be comfortable recommending expectant management at the request of the parent in situations where they felt certain of the diagnosis and believed antibiotics would provide clinical benefit. Gonzalez-Vallerjo<sup>56</sup> reported a similar finding.

#### ***4.1.4. Outcomes***

- *Clinical Outcome*

The vast majority of study children presenting with acute, non life-threatening illness were clinically improved within 48 hours of the initial ED visit. Two of the 628 children followed to 48 hours developed serious complications requiring hospitalization. Both children were diagnosed with viral illness, query AOM at the initial ED visit. One child was diagnosed with meningitis, (incidence of 1.6 per 1000) and one child with mastoiditis (incidence of 1.6 per 1000). The first child had documented moderate hearing loss 6 months after the ED visit, while the second child had no documented sustained

adverse outcomes at six months follow up. In the pre-antibiotic era, the incidence of meningitis and mastoiditis following from untreated AOM was close to 2.5 per 1000<sup>73-74</sup>. In both cases, the discrepancy in diagnosis between physicians (whether resident and attending physician, or generalist and specialist), suggested that the level of diagnostic certainty was low. In contrast to the study of Gonzalez-Vallejo<sup>56</sup> where physicians were more likely to prescribe antibiotics in conditions of low diagnostic certainty, antibiotics were not prescribed in either case at the initial ED visit. The mother of the younger child was given a prescription to fill at her discretion. In the case of the older child, the mother did not consult the ED despite growing concern that her daughter's condition was progressively deteriorating, because she was told to return to the ED at 48 hours. This provides physicians with caution when discussing the watch and wait option, and suggests that the wording of advice regarding reconsultation needs to be carefully considered.

Eighty-nine (35%) of children diagnosed with AOM missed one or two days of school or day care related to the illness episode. Working parents were affected, as most missed a day of work to care for their children. This was a crude measure of the functional impact of the illness on the family. Few studies have examined this factor, despite the burden of illness at the community level secondary to the high prevalence of this disease. This area requires further study, and an RCT examining the equivalency of antibiotics and expectant management will address this outcome in greater detail<sup>90</sup>.

One hundred and forty-two (22%) of the 628 parents followed to 48 hours had consulted their own family physician within 48 hours of the ED visit. This included 54 (22%) parents of 255 children diagnosed with AOM. Fifteen of these 54 children received

antibiotics at the second MD visit. Seven of the 29 parents who received a prescription for antibiotics filled it within 48 hours because their child's symptoms were not improving. Although not confirmatory, these figures suggest that the actual rate of antibiotic use in the study cohort diagnosed with AOM may be closer to 228/261 (87%). It is interesting that such a large proportion of parents consult their own physician within 24 hours of the ED visit. Although the reasons for this are not clear, it did not seem to be a reflection of dissatisfaction with the ED care, or doctor shopping for the desired treatment. In most cases, it served to reassure the parent that the child was getting better (by physician examination of the middle ear), or in some cases, fulfill a parental sense of obligation to share information about the child with the family doctor.

- *Satisfaction with ED Visit*

Most parents reported that they were satisfied with the treatment decision and the decision making process, once their child was examined by the physician. Most parents wanted to be provided with information about the treatment options and the signs to judge whether the child was improving or needed to be seen again by a physician. Few parents actually wanted to make the treatment decision. This supports the findings of Deber<sup>88</sup>, who has primarily examined the role of adult patients making personal treatment decisions in chronic or life-threatening illness. The physician's communication style with the child and parent was very important. Parents consistently mentioned dissatisfaction when they perceived that the physician failed to establish rapport with the child.

Almost all parents voiced a negative opinion about the ED waiting time. Parents expected that a physician would examine their child shortly after arrival in the ED. Many parents

who presented in the middle of the night did so because they believed their child needed immediate medical intervention. Some parents consulted the ED on the recommendation of their own physician's office or the emergency health line, and did not expect to wait "in line" to see the physician. Some parents feared that their child would "catch the germs" from other sick children in close quarters in the crowded waiting room. Most parents suggested that ED staff provide updated information about the estimated waiting time so that they could make a phone call, go for a cup of coffee or a walk without losing their "spot in line". Several parents provided recommendations for improving the flow of patients through the ED. The ED provides triaged care such that the most urgent cases are evaluated immediately in the main section of the department, and less urgent cases are reviewed in consecutive fashion in an area of the department run as a doctor's office (Child Health Center). ED physicians expressed different views about the expected waiting time for non-urgent conditions. Several physicians indicated that parents should expect to wait at least 2 hours prior to medical examination for suspected AOM<sup>47, 48</sup>.

#### ***4.1.5. Study Limitations***

##### ***4.1.5.1. Threat to Internal Validity***

###### ***1. Physician Response Rate on Baseline AOM Questionnaire***

Completed questionnaires were available for 69% (24/35) of physicians providing clinical service in the ED. All full time physicians completed the questionnaire. The physicians who declined to participate in the study provided clinical service on only an infrequent basis (once a month). Therefore, it is not likely that their practice would significantly alter the study results. However, the study findings reflect only the practice of the study physicians.

## ***2. Physician Response Rate on Clinical AOM Questionnaire***

Clinical AOM Questionnaires were completed for 55% (163/296) of the AOM diagnoses.

Possible reasons for the low physician response rate include:

- Lack of time to complete questionnaire, given the clinical workload in the ED. The 3-item questionnaire was specifically designed to be as brief and as easy to complete as possible to avoid infringing on clinical time. In discussion with ED physicians after data analysis, physician group endorsed this explanation for the low response rate. The physician group suggested that the questionnaire response rate was comparable to that achieved in other research projects completed in the department.
- Lack of study awareness. The investigator attempted to inform and remind all ED physicians, either by individual in-service, group presentation, or written instructions, of the study at the outset and through monthly updates. All study physicians completed at least one Clinical AOM Questionnaire, suggesting that lack of awareness did not account for the low response rate.
- Questionnaire unavailable. The registration clerks attached a copy of the study questionnaire on each medical chart of a study child. Often an incomplete questionnaire was collected, suggesting low response rate was not a function of questionnaire availability
- Physician disinterested in study
- Physician uncertain of diagnosis, therefore less likely to complete the questionnaire. The extent to which this is true is not known. Although completed questionnaires showed a range of diagnostic certainty values, the median values were high (positively skewed toward “10”) in children diagnosed with AOM. If questionnaires

were not completed in the uncertain diagnoses, this would certainly bias the results obtained. When the children diagnosed with AOM for whom diagnostic certainty ratings were and were not available were compared, the two groups did not differ with respect to the parent diagnosis, duration of symptoms, presence of symptoms, age of child, or treatment decision. Therefore it seems less likely that physician assessment of diagnostic certainty was a significant factor in questionnaire completion.

### ***3. Outcome Child Data***

Forty-four (15%) of the 296 parents of children with AOM requested no follow up interview at the time of study enrollment. Although these children and their parents may have been systematically different from those parents who agreed to (and in fact wanted) follow up telephone calls, it may safely be assumed that no significant complications were encountered by this group, as none of these children returned to the ED for reexamination.

### ***4. Validity of the Study Questionnaires***

All questionnaires were specifically developed for the study. An expert panel of physicians assessed the content validity of the physician questionnaires. This was done in a cursory fashion by a small volunteer group of parents for the parent questionnaire. The content of the questionnaires reflects concepts identified as significant to parent and physician decision making in AOM in the literature and discussions with experienced physicians.

Areas insufficiently addressed, with suggested improvements, include the following:

*Parent AOM Questionnaire*

- i. Risk factor exposure
- ii. Symptom Presentation; e.g. all symptoms need to be operationally defined, clarification of response options to allow accurate analysis of symptoms in combination ; i.e. fever and ear pain, fever and irritability, ear pain and sleep disturbance etc.
- iii. Reason for ED presentation needs to be more specific, and again inclusive, rather than exclusive. Parents often came for more than one reason, and this was not well-defined in the questionnaire
- iv. Medication Administration; e.g. more specific data regarding type and frequency of medication administered prior to ED presentation
- v. AOM history; e.g. number of previous episodes, laterality
- vi. Parent treatment expectation more carefully solicited

*Clinical AOM Questionnaire*

- i. Standardization of diagnosis through use of photographs and/or standardized checklist and/or use of tympanometry would enable assessment of reliability and validity of AOM diagnosis
- ii. Scaling of response options regarding the impact of factors on treatment decision difficult to interpret by researcher

*Physician Baseline Questionnaire*

- i. In hypothetical scenarios, add question about diagnosis first, and then treatment decision, to sort out whether treatment decisions reflect fact that physicians don't

think case is AOM, or are adopting expectant management in AOM. This is not clear in the current version

Further work on the questionnaires is needed to ensure that questions are tapping significant concepts in a reliable and valid fashion.

### ***5. Clinical Score Development***

This work should be considered a preliminary step in the process to assist study ED physicians in predicting AOM diagnosis and antibiotic prescribing decision in AOM. The study provides a description of the relationship between selected child, parent and physician variables and the AOM diagnostic and treatment decisions. More rigorous measurement of child clinical symptoms, with the addition of otoscopic variables, is necessary to produce a valid scoring system to aid prediction.

- Laupacis<sup>81</sup> states that the outcome predicted by a clinical rule, or score, should be clearly defined. A lack of an objective gold standard for the diagnosis of AOM is problematic. In this study, AOM diagnosis was based on the clinical judgment of each physician. Physical symptoms were not well defined, as ear pain and fever depended on parent definition rather than objective measurements. There was no attempt to assess inter-physician reliability, or validity against a bacteriologic standard. This lack of standard outcome definition makes clinical decision making in otitis media so difficult. Perhaps the introduction of a standardized diagnostic checklist, complete with standard photographs as response options from which to evaluate each child, would improve the validity of the diagnoses, and allow reliability testing across physician groups.

- Small numbers of children treated with a watch and wait strategy may have produced unstable risk estimates in the antibiotic prescribing decision model. Concato<sup>89</sup> states that a low (less than 10:1) ratio of outcome events to independent variables makes the risk estimates uncertain. An 11.3:1 ratio in this model suggests a problem of overfitting the data. A RCT equivalency trial of antibiotic therapy versus watchful waiting will provide clinical baseline data (demographic, physical symptoms, otoscopic findings). The obtained data for the WW group will be used to generate a clinical score predicting which children will fail expectant management within 72 hours of diagnosis, and therefore require antibiotic therapy. This data will presumably provide more clearly defined, systematically collected data to generate a more valid score. This score could then be validated in subsequent research. The performance characteristics of the clinical scoring system for diagnosis and prescribing developed in this study may be compared to the RCT-derived scoring system.
- Validation of the clinical scoring system is necessary prior to recommendation for use in the clinical setting. Methods of internal model validation include data splitting, cross validation and bootstrapping. Data splitting refers to the development of the model (variable selection, estimation of regression coefficients) on a random portion of the sample, and testing of the coefficients on the remaining portion of the sample. Cross validation is repeated data-splitting. Bootstrapping is an alternative method of internal validation that involves taking a large number of samples with replacement from the original sample. External validation involves testing the model on a different sample.

#### ***4.1.5.2. Threats to External Validity***

The major threat to the external validity of the study findings is the failure to adequately recruit a representative proportion of the population of children diagnosed with AOM in the study period. Only 296 of the 768 children diagnosed with AOM were enrolled in the study. Reasons for failure to recruit 490 children involve the inclusion criteria and the recruitment procedure.

Study inclusion criteria were selected on the basis of their presumed ability to identify children who would be diagnosed with AOM. It appears that symptoms of ear pain, sleep disturbance and ear pulling were the criteria that significantly predicted the AOM diagnosis. Other factors, especially feeding disturbance, failed to identify the target population. In the future, it may be prudent to drop the feeding disturbance criterion from the list of inclusion criteria.

Reasons for failure to recruit the missed cohort are not clear. Most of these children were not identified as eligible, even though they did not present with symptoms significantly different from the inclusion criteria. Thirteen percent of the children not recruited presented with a chief complaint that did not meet the study inclusion criteria. This group included 22 children with breathing problems, 5 children with rash and 5 children with abdominal pain. A proportion of parents (approximately 10%) was not recruited on the basis of language. Other invited parents simply were not interested in completing questionnaires in the ED. The daily recording of the number of parents and children deemed eligible but who declined study participation was not consistently performed by the registration clerks. The overnight registration clerks responsible for patient registration and study recruitment may have been less aware of (or less committed to) the

study as in-service training and data collection and monitoring was conducted during the day and evening. The retrospectively identified cohort was significantly younger, and presented with more non-specific signs, such as fever. Parents of these children may have been less likely to suspect an ear infection, and therefore less likely to be interested in the study, if they were asked. However it seems that other issues may have played a role in the failure to recruit this cohort, such as:

- i. Disinterest in study on part of registration clerk(s)
- ii. Acuity in the ED , though the two groups did not significantly differ in their time of presentation (whether time of day, or weekday versus weekend)

The study findings may not reflect those of the population of children presenting to the ED because of the large number of missed children. Children not recruited, but diagnosed with AOM, were more likely to be treated with immediate antibiotics than were the study children. The findings are also not generalizable to the community at large. It would be very interesting to compare the decision-making processes in a tertiary care center with those in an office-based community practice or a community walk-in clinic.

#### ***4.1.6. Implications***

The study findings emphasize the complexity of parent and physician decision making in the context of a prevalent, acute but not life-threatening childhood illness. To date, decision making in health care has primarily focused on the clinical encounter between an adult facing choices about treatments in chronic or life threatening (cancer) illness with his/her physician <sup>88</sup>. The decision- making processes addressed in this study are complex and multifaceted with implications for the child, family and health care system.

The study results have implications for the care of these children, physical and cognitive. The study also has implications for the primary prevention of AOM. The study results were similar to those of other studies in that parents' perceptions of the nature of the illness and its treatment affect a child's well-being. It is important to reassure the parents' appraisal of their child's illness. The study also found parents with children that the IHCED did not reassess their child and the associated morbidity, discomfort and disability at a time when their child's health and well-being were not optimal.

The study examined the associations between clinical symptoms reported by the parent and the physician diagnosis. A child presents with physical signs that trigger a set of diagnostic possibilities that may or may not suggest an examination of the middle ear. If available, the otoscopic findings are interpreted in light of the physical signs and parent history to refute or confirm a diagnosis of AOM. This study found that the presence of ear pain and the absence of fever increased the likelihood of a diagnosis of AOM. In reality, it is likely the association between a clinical sign or combination of signs and an otoscopic finding(s) that tips the balance in favor of a diagnosis of AOM over competing diagnostic possibilities. The failure to link physical signs with otoscopic findings limits valid prediction of the physician diagnostic and treatment decisions.

Practice change is a complex process involving a change in knowledge, attitudes and behaviors.<sup>70-73, 86</sup> A physician must be aware of evidence that challenges his/her current practice, weigh the risks and benefits involved in the decision to change or continue to practice in the same fashion, and consciously make a behavioral change. Currently, there is no clear consensus in the medical community regarding the diagnosis and optimal treatment of AOM. The evidence may be confusing for the ED physician, for whom

AOM represents a small proportion of his practice. Diagnostic accuracy in AOM is elusive, as there is no objective gold standard in routine practice. Strategies designed to promote practice change must consider the identified differences in the probability of AOM diagnosis in similarly presenting children noted between part time and full time physician groups. A first approach to understanding these differences may be a discussion of the findings directly with the study physicians. Differences may reflect variables not addressed in the study. Next, it may be prudent to discuss the lists of diagnostic criteria generated by the study physicians, and more importantly, their operational definitions and application in clinical practice. A hands-on diagnostic workshop, using the pneumatic otoscope with actual patients, may improve the consistency of diagnosis across the study physicians. The introduction of a standardized physical and otoscopic examination checklist, with photographs, such as the one to be used in the equivalency trial, may also improve both intra and inter-physician diagnostic reliability and validity.

Once a diagnosis is rendered, a physician faces conflicting evidence about what treatment option is best in the individual case. The physician must risk the chance of complications of not treating with antibiotics in order to diagnose viral or bacterial etiology of the AOM. Professional medical bodies, textbooks and treatment guidelines continue to advocate antibiotic therapy as the choice of treatment, while at the same time more and more journal articles, editorials and research reports question the validity of its use in all cases and suggest over use will harm the community. Prediction of the child who requires antibiotic therapy is difficult. In this study, the presence of ear pain and fever increased the likelihood of antibiotic prescribing. Adequate pain control obtained through education

of parents and physicians may decrease the demand for antibiotic use for this indication. A parent guideline about analgesia treatment may be useful in this regard. A workshop to educate physicians about the current state of the evidence may stimulate critical appraisal of current prescribing practice. Direct feedback about the discrepancies between estimated and actual prescribing rates may also serve this purpose. Further evidence in the form of a funded randomized controlled equivalency trial<sup>90</sup> to evaluate the safety and effectiveness of expectant management compared to antibiotic therapy, with this investigator as a member of the Steering Committee, will provide physicians with sound evidence to guide management decisions in this acute childhood illness.

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## **Appendix A**

## **Stages of Decision Making in Acute Otitis Media**

**Decision 1: Parent Decision**  
to seek medical consultation  
in emergency department

**Decision 2: Physician Diagnosis**  
of Acute Otitis Media or Other Illness

**Decision 3: Physician Decision** to prescribe  
antibiotic therapy or recommend watchful waiting

Conceptual Framework

# **Factors contributing to Parent Decision to Seek Medical Consultation in the Emergency Department**

**Parent Assessment of the Meaning  
of the Child's Symptoms, and their  
Potential Threat to Child's Well Being**

**Parent Decision to Seek Medical Consultation  
in the Emergency Department**

**Parent Judgment of Ability to  
Manage Child's Symptoms**

**Availability of Usual Health Care Resources**

**Conceptual Framework**

**Factors Contributing to the Physician  
Decision to Diagnose AOM or Other Illness**

**Child Factors**

**Parent Factors**

**Physician Diagnosis of  
AOM or Other Illness**

**Physician Factors**

**Environment Factors**

**Conceptual Framework**

# Factors contributing to the Physician Decision to Prescribe Immediate Antibiotics in Children Diagnosed with AOM

**Child Factors**

**Diagnostic  
Certainty**

**Parent Factors**

## Physician Prescribing Decision

**Physician Factors**

Conceptual Framework

## **Appendix B**



**Children's Hospital of Eastern Ontario**  
**Hôpital pour enfants de l'est de l'Ontario**

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

February 17, 1998

Ms. Jacqueline Page  
Department of Epidemiology  
University of Ottawa  
INTRA

**Re: Proposal 98/07E - A Descriptive Study of Parent and Physician Treatment Decisions for Children with Acute Otitis Media Presenting to a Pediatric Emergency Care Facility**

Dear Ms. Page:

I would like to thank you for your letter of February 13, 1998, and the revised copy of the Consent for the above-mentioned proposal.

Please accept this letter as written approval from the Research Ethics Committee for these changes.

It is your obligation to notify the REC prior to the institution of any modifications to this study, or any adverse events which may occur during the course of this study.

To ensure that the REC is kept informed of the progress of clinical studies, we request a yearly progress report from each investigator.

Sincerely,

D. Palframan, M.D., F.R.C.P.(C)  
Chair  
Research Ethics Committee

Terry P. Klassen, MD, MSc, FRCPC  
Director / Directeur

Mr. R. Thomas  
C.H.E.O. Trustee /  
membre du conseil  
d'administration de l'HEEO

## THE DIAGNOSIS AND TREATMENT OF CHILDREN WITH SUSPECTED EAR INFECTIONS: PARENTS' POINT OF VIEW

Ms. P. Brazeau  
Administrative Assistant /  
Adjointe administrative

Phone (613) 737-5555  
Fax (613) 738-4000

### DEAR PARENTS:

My name is Jacqueline Page and I am a Master of Science student in the Department of Epidemiology at the University of Ottawa. I am conducting a study to learn more about how ear infections are diagnosed and treated in the Emergency Department at the Children's Hospital of Eastern Ontario.

#### What is the purpose of the study?

- To identify ways in which parents "diagnose" an ear infection in their child
- To describe how parents decide to bring their child to the CHEO emergency department for treatment of an ear infection
- To describe the kinds of treatments parents think their children need

#### Who is invited to participate?

All parents or legal guardians who think their child has an ear infection

#### What's involved?

All parents will be asked:

- To fill out a 3-page form in your choice of English or French about your child's illness today while waiting to see the doctor. This should take about 5-10 minutes to complete, and will in no way delay your child's medical exam.
- Speak with the researcher on the telephone two days from now, in your choice of English or French, for about 5 minutes. She will ask you how your child is, and how you feel about the treatment recommended for your child's illness at today's visit.
- Allow the researcher to review the medical record of your emergency department visit today

**What are the anticipated benefits for you and your child?**

You and your child may not benefit directly from being part of the study. However, your information may help improve the care provided in the emergency department in the future.

As you complete the form today, you may think of some questions about your child's illness to ask the doctor. This may lead to a more satisfying discussion about your child's illness with the doctor.

**Are there any risks associated with participation in the study?**

No. There are no known risks to you or your child related to the study.

**Is participation voluntary?**

Yes. Your participation is entirely voluntary. You and your child are free to withdraw from the study at any time. Your decision about participation will not affect the care you and your child receive today or in the future at The Children's Hospital of Eastern Ontario

**Will my information be kept confidential?**

Absolutely. You are assured that all information relating to you and your child will be kept confidential. All study forms will be coded by number, so that your name and your child's name will not appear on any form. All study forms will be stored in a locked filing cabinet, and only the researcher will have access to the forms. The researcher will not share any information with your doctor, although you are free to do so if you wish.

**How will the information collected be used?**

The information collected will be used to understand more about the process of diagnosing and treating ear infections, from parents' point of view, in CHEO emergency department. You and your child will not be identified in any report or publication resulting from this study.

**Would you like to receive a copy of the results?**

- Yes, I would like to receive a copy of the study results       No thanks

If yes, please print:

Your name:.....

Mailing Address:.....  
.....  
.....

Phone Number:.....

**If I have questions about the study, who do I contact?**

Please contact Jacqueline Page at 613-728-4521 now or at any time in the future if you have any questions about the study. The supervisor of the study is Dr. Terry Klassen, Director, CHEO Research Institute, and a doctor in the emergency department.

**If I have questions about the ethics of the study, who do I contact?**

You may contact the Chair of the Research Ethics Committee, for information regarding patient's rights in research studies at (tel.#738-3272); however, this person cannot provide any medical information with regard to this study.

I have read this consent form, and I agree to participate in the study.

.....  
Print Name of Parent or Legal Guardian

.....  
Signature of Parent or Legal Guardian

.....  
Date

.....  
Print Name of Witness

.....  
Signature of Witness

## **Appendix C**

## Acute Otitis Media Physician Questionnaire

### DRAFT

Your name:.....

Date Completed:.....Day / Month / Year

**The first four questions ask about your medical training and current practice:**

1. Please check the box that best describes your level of training:

- Resident ..... Year ..... Pediatric ..... Emergency Medicine .... Family Medicine
- Fellow in Training
- Pediatrician with Practice predominantly in Emergency Medicine
- Pediatrician with practice predominantly in other than Emergency Medicine
- Family Physician with training in Emergency Medicine
- Family Physician (or General Practitioner)
- Other

2. How many years have you been practicing in a pediatric emergency department?

..... years

3. How many hours do you work in the CHEO emergency department

in an average week? ..... hours

4. In addition to your practice in CHEO's emergency department, how many hours per month, on average, do you spend working in the following community settings:

- pediatrician office practice .....hrs per month
- family physician practice .....hrs per month.
- urgent care walk-in clinic .....hrs per month
- community health centre .....hrs per month
- other..... hrs per month

The next two questions ask you to describe how you diagnose acute otitis media in CHILDREN 3 MONTHS TO 2 YEARS OF AGE:

6. Please list the minimal findings in the parent or child history or clinical symptoms that must be present in order for you to make a diagnosis of acute otitis media?

Child 3 months - 2 years of age

- .....
- .....
- .....

7. Please list the minimal set of signs on physician examination of the ear that must be present for you to make a diagnosis of acute otitis media?

Child 3 months - 2 years of age

- .....
- .....
- .....

The next two questions ask you to describe how you diagnose acute otitis media in CHILDREN between 2 YEARS, 1 DAY and 13 YEARS OF AGE:

8. Please list the minimal findings in the parent or child history or clinical symptoms that must be present in order for you to make a diagnosis of acute otitis media?

Child 2 years 1 day - 13 years of age

- .....
- .....
- .....



The following five questions ask you to reflect on your **current management** of a first episode of acute otitis media in children 3 months to 2 years of age:

12. What is your first choice of treatment?

- Analgesia alone
- Antimicrobial alone
- Analgesia plus Antimicrobial
- Watchful Waiting X 48 hours with Analgesia, with follow up scheduled in 48-72 hours
- Watchful Waiting with Analgesia, with antibiotic prescription to be filled if parent thinks child no better in 24-48 hours
- Watchful Waiting, Analgesia, with Follow up determined by Parent
- Saline Nose Drops
- Other .....

13. If you prescribe antibiotics, what is generally your first choice of antibiotic therapy?

- "Amoxil" - Amoxicillin
- "Clavulin" - Amoxicillin-Clavulanate
- "Ceclor" - Cefaclor
- "Suprax" - Cefixime
- "Septra" - Trimethoprim-Sulfamethazole
- "Pediazole"- Trimethoprim-Sulfamethazole + Erythromycin

14. In what percentage of children 3 months to 2 years with first episode of acute OM are you prepared to recommend analgesia plus a 48 hour WATCH AND WAIT strategy?

.....%

15. In those children 3 months to 2 years for whom you advise a watch and wait approach, do you automatically preschedule a follow up visit in 48 hours in either the emergency department or with the family physician?

Yes

No

OR

16. Do you provide the parent with an antibiotic prescription to fill in 24 -48 hours if they think their child is not improving?

Yes

No

Other.....

The following five questions ask you to reflect on your current management of acute otitis media in children over 2 years of age:

17. What is your first choice of treatment, on average?

Analgesia alone

Antimicrobial alone

Analgesia plus antimicrobial

Watchful waiting X 48 hours plus analgesia, follow-up scheduled at 48-72 hours

Watchful waiting, with antibiotic prescription to be filled if parent thinks child no better in 24-48 hours, analgesia

Watchful waiting, analgesia, with follow up determined by parent

Saline Nose drops

Other

describe:.....

18. In those children for whom you prescribe antibiotics, what is generally your first choice of antimicrobial therapy?

- "Amoxil" - Amoxicillin
- "Clavulin" - Amoxicillin-Clavulanate
- "Ceclor" - Cefaclor
- "Suprax" - Cefixime
- "Septra" - Trimethoprim-Sulfamethazole
- "Pediazole"- Trimethoprim-Sulfamethazole + Erythromycin
- Other (please specify).....

19. In what percentage of children over 2 years with acute OM are you prepared to recommend analgesia plus a 48 hour WATCH AND WAIT strategy?

.....%

20. In those children over 2 years of age for whom you advise a watch and wait approach, do you automatically preschedule a follow-up visit in 48 hours in either the emergency department or with the family physician?

- Yes
- No

OR

21. Do you provide the parent with an antibiotic prescription to fill in 24 -48 hours if they think their child is not improving?

- Yes
- No
- Other.....

22. In what percentage of **all children** that you diagnose with acute otitis media do you currently prescribe antibiotics?

.....%

The following five questions present some typical **clinical scenarios**. In all cases, adequate analgesia is prescribed. Please check the box beside the **additional treatment you would recommend**.

17. **Clinical Scenario #1:** A mother brings her 11 month old son to emergency as she is worried about a fever of 38.5 persisting for the last 24 hours. The child is irritable and crying, and allows you only a glimpse at his right tympanic membrane, which you think looks red:

**Would you choose to:**

- Follow up in 24-48 hours or sooner **OR**  Initiate treatment with antibiotics if signs of deterioration

18. **Clinical Scenario #2:** A father brings his 30 month old son to emergency. The boy attends day care, has had rhinitis for the last four days, is not sleeping, is irritable, tugging at his left ear, and has developed a fever of 38.5 in the last 24 hours. On exam, you see that his right tympanic membrane is red, with no light reflex:

**Would you choose to:**

- Follow up in 24-48 hours or sooner **OR**  Initiate treatment with antibiotics if signs of deterioration

19. **Clinical Scenario #3:** A father brings his 30 month old daughter to emergency. Like the case you have just examined, the girl attends day care, has had rhinitis for the past four days, is not sleeping well, is now irritable and tugging at her left ear. In contrast to the previous case, this girl has had a low grade fever for the past four days. Her tympanic membranes both look red.

**Would you choose to:**

- Follow up in 24-48 hours or sooner if signs of deterioration      **OR**       Initiate treatment with antibiotics

20. **Clinical Scenario #4:** A mother brings her 11 month old son to emergency. He has had a fever of 39 C for 48 hours, is crying and irritable, has definite rhinitis and some wheezing. On exam, both tympanic membranes are red and slightly bulging, though you are unable to get a great look:

**Would you choose to:**

- Follow up in 24-48 hours or sooner if signs of deterioration      **OR**       Initiate treatment with antibiotics

21. **Clinical Scenario #5:** You are asked to examine a crying 18 month old girl. Her mother tells you that her daughter has had a cold for the past 2 days, and a fever of 40 for the last day. On exam, you find no signs of meningismus and no other focus of infection. A chest X ray and urinalysis are negative. The child won't let you examine her ears:

**Would you choose to:**

- Follow up in 24-48 hours or sooner if signs of deterioration      **OR**       Initiate treatment with antibiotics

22. **Clinical Scenario #6:** You next examine a 24 month old child. She presents with a 24 hour history of rhinitis and fever of 38.5, for which she was sent home from her daycare. On exam you note that both tympanic membranes appear to be bulging. You cannot find any other focus of infection. Her parents would like a prescription for antibiotics as they are unable

to take more time off work.

**Would you choose to:**

- Follow up in 24-48 hours or sooner if signs of deterioration      **OR**       Initiate treatment with antibiotics

**23. Clinical Scenario #7:** Lastly, you see an 18 month old boy who is irritable and crying. His parents tell you that he has had a fever of 39 for the last 24 hours. On exam you see a yellow and bulging tympanic membrane on the right, the left looks red.

**Would you choose to:**

- Follow up in 24-48 hours or sooner if signs of deterioration      **OR**       Initiate treatment with antibiotics

The following questions ask you to consider factors that may influence your treatment decisions in acute otitis media:

**24.** Sometimes parental expectations regarding a particular treatment influence physicians' treatment recommendations. Over the past year, in what percentage of cases would you estimate that your choice of treatment has been altered by parental preferences?

0%.....25%.....50%.....75%.....100%.

**25.** To what degree are you concerned about the increasing emergence of antibiotic-resistant bacteria in your practice?

- I'm globally concerned, but this doesn't influence my decision with my patients  
 I'm globally concerned, and make an effort to minimize antibiotic use with my patients

I do not perceive this to be a major problem in Canada

26. How does your concern about antibiotic-resistant bacteria influence your clinical treatment decision for individual children with acute OM?

|   | In Progress<br>of doing  | Not Currently<br>doing   |
|---|--------------------------|--------------------------|
| I am starting to reconsider my antibiotic prescribing behavior                          | <input type="checkbox"/> | <input type="checkbox"/> |
| I am asking my colleagues for their opinion on this problem                             | <input type="checkbox"/> | <input type="checkbox"/> |
| I am reviewing the literature to increase my knowledge                                  | <input type="checkbox"/> | <input type="checkbox"/> |
| I am starting to adopt a watch and wait approach in selected cases                      | <input type="checkbox"/> | <input type="checkbox"/> |
| I am trying to educate my colleagues to reduce inappropriate prescribing of antibiotics | <input type="checkbox"/> | <input type="checkbox"/> |

27. What do you estimate is the probability that a child diagnosed with acute otitis media and not treated with antibiotics will develop mastoiditis in Ottawa?

.....

28. What do you estimate is the probability that a child diagnosed with acute otitis media and not treated with antibiotics will develop meningitis in Ottawa?

.....

29. In cases in which you advise a watchful waiting strategy and have no followup appointment booked, how concerned are you that you may miss a bacterial infection that progresses to mastoiditis or meningitis?

- Extremely concerned
- Somewhat concerned
- Neutral
- Somewhat unconcerned
- Not At All concerned

30. Would your degree of concern change if you were able to ensure a follow up visit?

- Yes                       No

How?.....

31. Please rate the importance (1=not at all important; 3 = important; 5 = very important)of the following factors in your current treatment decisions in AOM

|   | <u>Not at all</u> |   |            |   |              |
|---|-------------------|---|------------|---|--------------|
|   | <u>Imp</u>        |   | <u>Imp</u> |   | <u>V.Imp</u> |
| a) Time Pressure (not enough time to discuss dx, alternatives)                    | 1                 | 2 | 3          | 4 | 5            |
| b) Parental Expectations  | 1                 | 2 | 3          | 4 | 5            |
| c) Scientific evidence  | 1                 | 2 | 3          | 4 | 5            |
| d) Professional Standard of practice  | 1                 | 2 | 3          | 4 | 5            |
| e) Respected colleague or expert practices this way                               | 1                 | 2 | 3          | 4 | 5            |
| f) Worry about potential complications arising from not treating with antibiotics | 1                 | 2 | 3          | 4 | 5            |
| g) No current mechanism to schedule follow-up                                     | 1                 | 2 | 3          | 4 | 5            |
| h) Standard of practice in emergency dept   | 1                 | 2 | 3          | 4 | 5            |

29. Parents differ in their expectations about what treatment is needed for their children. Thinking about the parents of children you have diagnosed with acute OM during the last six months, please estimate the percentage of parents who fit into the following categories:

(total should add to 100%)

|   | <u>% of parents</u> |
|---|---------------------|
| a) The parent asks for a prescription for antibiotics   | .....               |
| b) The parent does not express any treatment preference | .....               |
| c) The parent states a preference for watchful waiting  | .....               |
|   | <b>Total 100%</b>   |

30. Parents differ in their expectations about their own involvement in the treatment decisions for their children. Thinking about the parents of children you have diagnosed with AOM in the last six months, please estimate the percentage of parents who fit into the following categories (% parents should add to 100%). Please indicate your level of comfort with each category by circling the appropriate number; 1=very uncomfortable, 3= neutral, 5= very comfortable

|   | <u>% of parents</u> | <u>Level of comfort</u> |   |   |
|---|---------------------|-------------------------|---|---|
| a) After hearing treatment alternatives and my opinion, parents make the decision                           | .....%              | 1                       | 3 | 5 |
| b) The parent wants to make a decision together with me considering their social, work and family situation | .....%              | 1                       | 3 | 5 |
| c) The parent wants me to make the decision   | .....%              | 1                       | 3 | 5 |

31. Do you think a parent-focused information sheet dealing with the risks and benefits of treatment alternatives would make your discussions with parents easier?

- Yes
- No
- Don't Know

Why or why not?

.....

The following two questions refer to the way you tend to adapt to change:

32. Physicians vary in the rate at which they adopt new ways of doing things. Compared with the your colleagues in the CHEO emergency department, please circle the number that best describes your general attitude towards change in medical care.

|  |   |   |   |   |
|--|---|---|---|---|
| 1  | 2 | 3 | 4 | 5   |
| I am among the 1st<br>first in my group to<br>change my practice |   |   |   | I am among the last<br>to make changes in<br>medical practice |

33. In relation to other CHEO emergency department physicians, please describe yourself on the following scale:

|                                       |   |   |   |                                       |
|---------------------------------------|---|---|---|---------------------------------------|
| 1                                     | 2 | 3 | 4 | 5                                     |
| I tend to have<br>a "leadership role" |   |   |   | I tend to have a<br>"Followship" role |

The following questions ask you whether you are prepared to reevaluate your current treatment recommendations in light of the existing scientific evidence:

34. Are you familiar with the meta-analysis: Are antibiotics indicated as initial treatment for children with acute otitis media? by Del Mar C, Glasziou P, Hayem M; BMJ. 1997; 314: 1526-29 (also available in the Cochrane Library Database of Systematic Reviews 1997 edition?)

Yes       No

35. How strongly do you agree with the conclusions of the Del Mar meta-analysis that state that 17 children need to be treated with antibiotics in order to prevent one child from experiencing pain 2-7 days after presentation?

- Strongly agree
- Somewhat agree
- Don't know
- Somewhat disagree

- Strongly disagree

Why?

.....

36. Would you consider changing your treatment recommendations from antibiotic therapy to a watch and wait strategy on the basis of the Del Mar conclusions?

- Strongly consider
- Possibly Consider
- Neutral
- Would definitely not consider
- Don't know

37. Do you think a clinical practice guideline on the treatment of acute OM created by you and your colleagues is needed to improve the care provided in the CHEO emergency department?

- Yes
- No

Why or why not?

.....

38. Do you think a randomised clinical trial comparing antibiotic therapy to a watch and wait approach is needed before you personally consider changing your treatment recommendations?

- Yes
- No

Why or why not?

.....

**THANK YOU very much for your time and information. Your contribution to this effort is greatly appreciated.**

Physician Questionnaire - Acute Otitis Media Study DRAFT

code

1. How certain are you of the diagnosis of Acute OM in this child?

Not at all certain

Absolutely certain

1.....5.....10

2. What treatment did you recommend for this child?

Yes No

- Analgesia
Antibiotics prescribed
Watch & Wait: parent given prescription to fill if child no better in 24-48 hrs
Watch & Wait: parent to return to GP or emergency if child no better
Watch & Wait: parent given follow up appointment for 24-48 hours

3. Please rate the influence (1 = no influence; 5 = extremely influential) of the following factors to your treatment decision:

a) My perception of the parent(s) ability to follow through on recommendation

1 2 3 4 5

b) My perception of what treatment the parent expected today

1 2 3 4 5

c) My judgement of the severity of clinical symptoms

1 2 3 4 5

d) My interpretation of ear findings on otoscopic exam

1 2 3 4 5

e) Child's Age

1 2 3 4 5

f) My concern about the potential development of complications if I do not treat this child

1 2 3 4 5

THANK YOU VERY MUCH FOR YOUR TIME AND INFORMATION. Please return completed form to the admitting clerk.

## Ear Infection Parent Questionnaire DRAFT

**CODE**

**TODAY'S DATE:**.....day/month/year

**Your postal code:** ....

### THE FOLLOWING QUESTIONS ASK ABOUT YOUR CHILD'S ILLNESS TODAY:

1. Which of the following possible reasons were most important in your decision to bring your child to the emergency department today?

- | <b>Yes</b>               | <b>No</b>                |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | severity of my child's symptoms                           |
| <input type="checkbox"/> | <input type="checkbox"/> | duration of my child's symptoms                           |
| <input type="checkbox"/> | <input type="checkbox"/> | don't know what to do for my child                        |
| <input type="checkbox"/> | <input type="checkbox"/> | need a prescription for antibiotics for daycare or school |
| <input type="checkbox"/> | <input type="checkbox"/> | my child is not getting any better                        |
| <input type="checkbox"/> | <input type="checkbox"/> | fear that my child needs to be hospitalized               |
| <input type="checkbox"/> | <input type="checkbox"/> | don't have a family doctor                                |
| <input type="checkbox"/> | <input type="checkbox"/> | CHEO is more convenient                                   |
| <input type="checkbox"/> | <input type="checkbox"/> | family doctor unavailable                                 |
| <input type="checkbox"/> |                          | Other .....   |

2. What are your child's symptoms today? (May choose more than one)

- | <b>Yes</b>               | <b>No</b>                |            |
|--------------------------|--------------------------|------------|
| <input type="checkbox"/> | <input type="checkbox"/> | earache    |
| <input type="checkbox"/> | <input type="checkbox"/> | fever      |
| <input type="checkbox"/> | <input type="checkbox"/> | sorethroat |

- sleep disturbance
- pulling at ears
- irritability
- decreased feeding
- same as last time my child had this illness

please describe.....

3. Have you given your child any medicine today?

Yes No

- pain medicine
- medicine to reduce fever
- c o u g h medicine
- nose drops
- ear drops
- antibiotics from my doctor

4. When did you first notice your child getting sick?

- within the last 24 hours
- 25- 48 hours age (1-2 days ago)
- 2- 5 days ago

5. What do you think is the matter with your child?

.....

6. Has your child been sick like this before?

- Yes - go to Question 7
- No - SKIP TO QUESTION 13

7. How many times has your child been sick like this before?.....times

8. When was your child last sick like this? .....(month/year)

9. The last time your child was sick like this, did you see a doctor?

- Yes
- No -**SKIP TO QUESTION 13**
- Don't remember

10. Did the doctor prescribe antibiotics?

- Yes
- No-**SKIP TO QUESTION 13**
- Don't remember

11. Did you have any trouble giving the antibiotic medication to your child?

- Yes
- No

12. Do you think the antibiotics helped your child get better faster?

- Definitely
- Probably
- Don't Know
- Probably Not
- Definitely Not

13. Do you think your child would benefit from antibiotics today?

- Yes
- It depends on what the doctor thinks is best
- No
- Don't Know

**THE FOLLOWING QUESTIONS ASK ABOUT YOU AND YOUR HOUSEHOLD**

14. Are you the child's  mother  father  legal guardian
15. Is your child
- in daycare on a full-time basis
  - in daycare on a part-time basis
  - at home during the day
  - in school part or all day
  - with other kids in informal or home day care
16. Is your child exposed to tobacco smoke in your house or at the babysitter's home?
- Yes  No
17. Do you have a family physician?  Yes  No
18. What is your highest level of education attained?
- completed some high school
  - graduated from secondary school
  - graduated from college
  - graduated from university

**THANK YOU VERY MUCH FOR YOUR TIME AND EFFORT**

Please return this completed questionnaire to the admitting clerk or the nurse.

The researcher will phone you at home in TWO DAYS to see how your child is doing and ask you a few questions about your emergency department visit. The call will take approximately 5-10 minutes of your time.

Please check here if you do not wish to be called

The best time to call is:  morning  afternoon  evening

Would you prefer that your telephone call be in English .....or French.....?

Your PHONE NUMBER is:.....

## Étude sur les infections d'oreilles

### Questionnaire pour les parents

**DATE :** .....jour/mois/année

**Votre code postal:** .... .... .... .... ....

**Les questions suivantes sont au sujet de la maladie dont votre enfant souffre aujourd'hui:**

1. Pourquoi avez-vous amené votre enfant à la salle d'urgence de L'HEEO maintenant?

**OUI    NON**

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | à cause de la sévérité des symptômes de mon enfant                           |
| <input type="checkbox"/> | <input type="checkbox"/> | à cause de la durée des symptômes de mon enfant                              |
| <input type="checkbox"/> | <input type="checkbox"/> | je ne sais pas quoi faire pour mon enfant                                    |
| <input type="checkbox"/> | <input type="checkbox"/> | j'ai besoin d'une prescription pour un antibiotique pour la garderie / école |
| <input type="checkbox"/> | <input type="checkbox"/> | la condition de mon enfant ne s'améliore pas                                 |
| <input type="checkbox"/> | <input type="checkbox"/> | j'ai peur que mon enfant doive être hospitalisé                              |
| <input type="checkbox"/> | <input type="checkbox"/> | je n'ai pas de médecin de famille  |
| <input type="checkbox"/> | <input type="checkbox"/> | la salle d'urgence de l'HEEO est plus facile d'accès                         |
| <input type="checkbox"/> | <input type="checkbox"/> | mon médecin de famille n'est pas disponible                                  |

2. Quels sont présentement les symptômes que démontre votre enfant? ( Vous pouvez sélectionner plus qu'un choix)

**OUI    NON**

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | mal d'oreilles  |
| <input type="checkbox"/> | <input type="checkbox"/> | fièvre  |
| <input type="checkbox"/> | <input type="checkbox"/> | mal de gorge  |
| <input type="checkbox"/> | <input type="checkbox"/> | difficulté à dormir   |
| <input type="checkbox"/> | <input type="checkbox"/> | frotte / tire son oreille                                       |
| <input type="checkbox"/> | <input type="checkbox"/> | irritable   |
| <input type="checkbox"/> | <input type="checkbox"/> | perte d'appétit   |
| <input type="checkbox"/> | <input type="checkbox"/> | la même chose que la dernière fois qu'il/elle avait ce problème |
- S.V.P. décrivez:

.....  
.....

3. Quand vous êtes-vous aperçu que votre enfant n'était pas bien?

- durant les derniers 24 heures
- durant les derniers 25 - 48 heures
- durant les derniers 2 à 5 jours

4. Avez-vous donné des médicaments à votre enfant aujourd'hui?

OUI    NON

- médicaments pour la douleur
- médicaments pour réduire la fièvre
- médicaments pour la toux
- gouttes pour le nez
- gouttes pour les oreilles
- antibiotiques prescrit par mon médecin

5. De quoi pensez-vous souffre votre enfant?

.....

6. Votre enfant a-t-il/elle déjà eu des symptômes semblables auparavant?

OUI

NON

**SI VOUS AVEZ RÉPONDU "NON" SAUTEZ À LA QUESTION 12. SI "OUI" S.V.P. CONTINUEZ.**

7. Combien de fois? .....

8. La dernière fois que votre enfant a eu des symptômes semblables était ..... ( mois / année).

9. La dernière fois que votre enfant a eu des symptômes semblables, a-t-il/elle été traité avec des antibiotiques?

- Oui
- Non
- Je ne me souviens pas

**SI VOUS AVEZ RÉPONDU "NON" SAUTEZ À LA QUESTION 12. SI "OUI" S.V.P. CONTINUEZ.**

10. Avez-vous eu de la difficulté à administrer l'antibiotique à votre enfant?

- Oui
- Non

11. Pensez-vous que l'antibiotique a précipité la guérison de votre enfant?

- définitivement
- probablement
- je ne sais pas
- probablement que non
- définitivement non

12. Pensez-vous que votre enfant a besoin d'antibiotique maintenant?

- Oui
- Selon l'avis du médecin
- Non
- Je ne sais pas

### **LES QUESTIONS SUIVANTES SONT AU SUJET DE VOUS ET VOTRE FAMILLE**

13. Êtes-vous .....

- la mère
- le père
- tuteur légal

14. Est-ce que votre enfant fréquente...

- une garderie à plein temps
- une garderie à temps partiel
- demeure à la maison
- fréquente l'école ( partiellement / toute la journée )

15. Votre enfant est-il/elle exposé à la fumée du tabac dans votre demeure ou à la garderie?

- Oui
- Non

16. Avez-vous un médecin de famille / pédiatre?

- Oui
- Non

17. Quel est votre niveau d'éducation?

- école secondaire non complété
- gradué de l'école secondaire
- collège
- université

**MERCI POUR VOTRE TEMPS ET VOTRE PARTICIPATION**

Une infirmière associée à l'étude vous téléphonera **DANS DEUX JOURS** pour vous demandez quelques questions sur la condition de votre enfant ainsi que de votre visite à la salle d'urgence de l'HEEO. Cette entrevue prendra environ 20 minutes.

S.V.P. cochez si vous **NE** voulez pas que l'infirmière vous appel

**QUAND EST LE MEILLEUR TEMPS POUR VOUS CONTACTER? S.V.P. encerclez**

**AVANT MIDI**

**APRÈS MIDI**

**EN SOIRÉE**

**VOTRE NUMÉRO DE TÉLÉPHONE :.....**

**PRÉFÉREZ-VOUS QUE L'APPEL SOIT EN**

**Anglais**

**Français**

**S.V.P. RETOURNEZ LE QUESTIONNAIRE AU COMMIS DES  
ADMISSIONS. MERCI POUR VOTRE TEMPS ET VOTRE  
PARTICIPATION**

**Follow up Telephone Interview with Parent DRAFT**

conducted by investigator (English) or research assistant (French) two days following emergency department visit

1. How is your child feeling today?

.....

2. What symptoms are causing you to continue to worry about your child?

Interviewer to check all symptoms volunteered by parent (prompts What about.....?)

- earache
- sorethroat
- fever
- sleep disturbance
- pulling at ears
- irritability
- irritability only when lying flat
- decreased feeding
- Same as last time child was sick like this  
(Please describe.....)
- other (please describe.....)

3. What treatment did the physician in the emergency department prescribe for your child?

- watch and wait for 24 -48 hours, with parent to determine need for follow up
- antibiotics (for how long?.....)
- pain medicine
- referred you to a ear nose and throat doctor for tubes
- follow up with family doctor if child does not improve in 48-72 hours
- watch and wait, with prescription to fill if child not improving

4. How satisfied are you with the treatment decision (insert what was stated from question 3) that was made for your child?

- very satisfied
- somewhat satisfied
- neutral
- somewhat dissatisfied
- very dissatisfied

5. Do you feel that the emergency department doctor gave you as much information about your child's condition as you need to best care for your child?

- Yes
- No

If no, in what specific areas would you have liked more information?  
.....

6. Do you feel that the emergency department doctor provided you with the information about the recommended treatment you need to best care for your child?

- Yes
- No

If no, in what specific areas do you feel you need more information?  
.....

7. How involved were you in the treatment decision for your child?

- Totally involved
- Partially Involved
- Not really involved

8. How would you describe your involvement?

Yes    No

- Did you ask questions?
- Did the doctor answer your questions to your satisfaction?
- Did you suggest treatment preference or did the doctor?
- Who made the final decision?

9. How satisfied are you with your involvement in the treatment decision?

- very satisfied
- somewhat satisfied
- neutral
- somewhat dissatisfied
- very dissatisfied

If dissatisfied, what would you have liked done differently?

.....

.....

10. Have you experienced any difficulty in following the treatment recommended by the doctor in the emergency room?     Yes                     No

**IF YES, can you describe the nature of the difficulty?**

.....  
.....  
.....

11. How much time have you needed to take off work in order to care for your child?.....

12. Have you seen another doctor for advice and /or treatment after the emergency visit?

- Yes  No

13. Did you receive (or fill - if watch and wait strategy) a prescription for antibiotics following your visit to the CHEO emergency department?

- Yes  No

If child is still symptomatic, or parent has concerns or unanswered questions, researcher will advise parent to consult either family physician or the CHEO emergency department for reevaluation and advice

**Thank you very much for your time and for sharing your information.**

**Your contribution to this effort is greatly appreciated.**

**Would you like a copy of the results of this study mailed to you at the completion of the study?**

- Yes No**

**If yes, what is your full name and mailing address:**

.....  
.....

## **Appendix D**

**Appendix D: Relationship between Study Objectives and Questionnaire Content.**

**1. Relationship between Parent AOM Questionnaire Content and Study Objectives**

Table 1 shows the proposed relationship between the questions and the study objectives.

| <b>Questionnaire</b>            | <b>Questionnaire Content</b>   | <b>Study Objective</b>                                |
|---------------------------------|--|---|
| <b>Parent AOM Questionnaire</b> | <ul style="list-style-type: none"> <li>Demographic information</li> </ul>                            | <ul style="list-style-type: none"> <li>1</li> </ul>   |
|                                 | <ul style="list-style-type: none"> <li>Child clinical signs and symptoms observed at home</li> </ul> | <ul style="list-style-type: none"> <li>1</li> </ul>   |
|                                 | <ul style="list-style-type: none"> <li>Reasons for consulting ED</li> </ul>                          | <ul style="list-style-type: none"> <li>1</li> </ul>   |
|                                 | <ul style="list-style-type: none"> <li>Parent perception of the nature of the illness</li> </ul>     | <ul style="list-style-type: none"> <li>1</li> </ul>   |
|                                 | <ul style="list-style-type: none"> <li>Parent treatment preferences and expectations</li> </ul>      | <ul style="list-style-type: none"> <li>All</li> </ul> |

**2. Relationship between Physician Baseline Questionnaire Content and Study Objectives**

Table 2 shows the proposed relationship between the questions and the study objectives.

| <b>Study Questionnaire</b>              | <b>Questionnaire Content</b>  | <b>Study Objective</b>  |
|---|---|---|
| <b>Physician Baseline Questionnaire</b> | <ul style="list-style-type: none"> <li>Demographic Characteristics</li> </ul>               | <ul style="list-style-type: none"> <li>Objective 2</li> </ul> |
|   | <ul style="list-style-type: none"> <li>Diagnostic Criteria</li> </ul>                       | <ul style="list-style-type: none"> <li>2</li> </ul>           |
|   | <ul style="list-style-type: none"> <li>Current Management (Prescribing Behavior)</li> </ul> | <ul style="list-style-type: none"> <li>3</li> </ul>           |
|   | <ul style="list-style-type: none"> <li>Factors Influencing Management Decisions</li> </ul>  |   |
|   | <ul style="list-style-type: none"> <li>Strategies to Promote Practice Change</li> </ul>     |   |

*3. Relationship between Physician Clinical AOM Questionnaire Content and Study Objectives*

Table 3 shows the proposed relationship between the questions and the study objectives.

| <i>Study Questionnaire</i>                  | <i>Questionnaire Content</i>  | <i>Study Objective</i> |
|---|---|------------------------|
| <i>Physician Clinical AOM Questionnaire</i> | • Diagnostic certainty specific to each clinical diagnosis of AOM                       | • Objective 2          |
|   | • Management decision   | • 3, 6                 |
|   | • Influence of child's age on decision  | • 3                    |
|   | • Influence of perception that parents would adhere to treatment prescribed on decision | • 3                    |
|   | • Influence of perceived severity of symptoms on decision                               | • 3                    |
|   | • Influence of interpretation of otoscopic findings on decision                         | • 3                    |
|   | • Influence of fear of complications on decision  | • 3                    |
|   |   |                        |

*4. Relationship between Follow Up Telephone Interview Content and Study Objectives*

Table 4 shows the proposed relationship between the questions and the study objectives

| <i>Study Instrument</i>           | <i>Content</i>   | <i>Study Objective</i> |
|-----------------------------------|--|------------------------|
| <i>Parent Follow Up Interview</i> | • Determine the child's clinical outcome                                       | • Objective 6          |
|                                   | • Record parents' understanding of the treatment recommendation                | • 6                    |
|                                   | • Determine parents' adherence with the recommended treatment                  | • 6                    |
|                                   | • Record consultation with additional health care providers after the ER visit | • 6                    |
|                                   | • Measure the level of satisfaction with the treatment decision and            | • 6                    |

|  |                         |  |
|--|-------------------------|--|
|  | decision-making process |  |
|--|-------------------------|--|

*5. Relationship between Emergency Medical Consultation Record Content and Study Objectives*

Table 5 shows the proposed relationship between the content of the consultation record and the study objectives.

| <i>Study Instrument</i> | <i>Instrument Content</i> | <i>Study Objective</i> |
|-------------------------|---------------------------|------------------------|
| <i>Emergency Record</i> | • Child age and gender    | • 1                    |
|                         | • Time of presentation    | • 1                    |
|                         | • Chief complaint         | • 1                    |
|                         | • Clinical symptoms       | • 1, 2, 3              |
|                         | • Ooscopic findings       | • 2, 3                 |
|                         | • Management decision     | • 3                    |

## **Appendix E**

### Sample Size Calculation

In order to estimate the proportion of children presenting to the CHEO emergency department diagnosed with acute otitis media and treated with antibiotics, with a precision of 5% and 95% confidence, a sample size of 385 children is required. This is based on the most conservative estimate that the proportion of children with acute otitis media treated with antibiotics is 0.50.

The sample size calculation is based on the formula:

$$N = \frac{z^2_{(1-\alpha/2)} [(P)(1-P)]}{d^2} \quad \text{where } P=0.5, d=0.05 \text{ and } z=1.96$$
$$= \frac{(1.96^2) (0.5)(0.5)}{(0.05)^2}$$
$$= 385 \text{ subjects}$$

If one assumes that the proportion of children diagnosed with AOM is 0.80, then the sample size required is 246 children (precision 5%, confidence 95%).